

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 1, 2026

EDAP TMS SA

(Exact name of Registrant as specified in its charter)

France
(State or other jurisdiction
of incorporation)

000-29374
(Commission File No.)

98-1644844
(I.R.S. Employer
Identification No.)

Parc d'Activites la Poudrette-Lamartine
4/6, rue du Dauphiné
Vaulx-en-Velin, France 69120
(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (+33) 47-215-3150

Not Applicable

(Former name or former address if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
American Depositary Shares, each representing one Ordinary Share (Ordinary Shares, nominal value €0.13 per share)	FOCL	NASDAQ Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging Growth Company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item Regulation FD Disclosure.
7.01

As previously announced, spokespersons of EDAP TMS S.A. (the "Company") presented the information in the presentation attached hereto as Exhibit 99.1 at the FocalTherics Investor Day on June 1, 2026, which commenced at 8:00 a.m. ET and was open to all participants via live webcast through the Events and Presentations section of the Company's Investor Relations website. A replay of the webcast and associated slide presentation is available on the Company's website.

The information in this item and item 9.01 of this Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item Financial Statements and Exhibits.
9.01.

(d) Exhibits

Exhibit No. **Description**

99.1	FocalTherics Investor Day Presentation dated June 1, 2026
104	Cover Page Interactive Data File-the cover page XBRL tags are embedded within the Inline XBRL document

FocalTherics™

2026 Investor Day

Nasdaq (FOCL)

June 1, 2026

FocalTherics™ 1

FORWARD-LOOKING STATEMENTS & DISCLAIMER

This presentation is being furnished for informational purposes only and may be given in conjunction with an oral presentation. It should not be taken out of context. Unless the context requires otherwise, references to "FocalTherics," "the Company," "we," "us," and "our" refer to EDAP TMS S.A., operating under the corporate name FocalTherics™ (Nasdaq: FOCL).

The information contained in this presentation speaks only as of the date this presentation is made, is preliminary, subject to change, and reflects management's current expectations as of the date hereof. The Company undertakes no obligation to update or revise the information contained in this presentation, to conform these statements to actual results, or to make changes in the Company's expectations, except as required by applicable law.

In addition to historical information, this presentation contains forward-looking statements within the meaning of applicable federal securities laws, including Section 27A of the U.S. Securities Act of 1933 and Section 21E of the U.S. Securities Exchange Act of 1934. These include statements regarding the Company's business strategy, expected progress, expectations related to the Company's product candidates to treat various conditions, growth and expansion plans. Forward-looking statements may be identified by words such as "believe," "can," "contemplate," "could," "plan," "intend," "may," "might," "potential," "objective," "target," "project," "predict," "forecast," "guideline," "should," "will," "estimate," "expect," and "anticipate," or their negative or similar expressions. These statements reflect management's current expectations regarding future events and financial performance. Forward-looking statements are subject to inherent risks and uncertainties, including matters not yet known to us or not currently considered material by us that could cause actual results to differ materially from those expressed or implied. Important factors that could cause actual results to differ materially include, among others, the clinical status and market acceptance of the Company's High Intensity Focused Ultrasound ("HIFU") devices; risks associated with the intended discontinuation of the Company's Extracorporeal Shock Wave Lithotripsy ("ESWL") and Distribution operating segments, including that the discontinuation may take longer or cost more than expected, may result in disputes with customers, distributors, employees or other counterparties, and may not produce the strategic benefits anticipated; the rate and degree of market acceptance of the Company's products and therapies; the establishment and maintenance of favorable reimbursement and payment policies; the effects of increased competition; the ability to obtain required regulatory approvals; the development and protection of intellectual property; the successful completion of clinical trials; and risks associated with the current worldwide inflationary environment, the uncertain worldwide economic, political and financial environment, geopolitical instability, climate change and pandemics, or other public health crises, and their related impact on our business operations, including their impacts across our businesses or demand for our devices and services.

Additional risks are described in the Company's filings with the Securities and Exchange Commission, including under the headings "Cautionary Statement on Forward-Looking Information" and "Risk Factors" in the Company's Annual Report on Form 10-K and subsequent quarterly reports on Form 10-Q.

This presentation and the accompanying oral presentation also contain estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. The Company has not independently verified the accuracy or completeness of the data contained in these industry publications and other publicly available information. The Company makes no representations as to the accuracy or completeness of that data. In addition, projections, assumptions, and estimates of our future performance and the future performance of the markets in which we compete are necessarily subject to a high degree of uncertainty and risk.

FocalTherics is a medical device manufacturer and cannot and does not recommend specific treatment approaches. The clinical data presented herein is intended for informational purposes only. Individual patient results may vary. Patients should consult their physician to determine the appropriate treatment for their individual circumstances.

Certain physicians referenced in this presentation may have received consulting fees, research grants, or other compensation from FocalTherics.

Agenda

1 RYAN RHODES
CEO

Transformation of EDAP | Focal One®
Our Next Chapter as FocalTherics™

**Commercial Leader in Robotic
Focal Therapy: Prostate Cancer**

**Clinical Expansion of Our Focal
Therapy Platform: BPH and
Endometriosis**

2 BEHFAR EHDAIE, MD, MPH
Memorial Sloan Kettering Cancer Center

**Clinical Experience with Focal One
Robotic HIFU**

3 STEVE ANNEN
EVP Product Management

Innovation and Advanced Technologies

4 KEN MOBECK
CFO

Financials: Positioned for Growth

5 ALL

Closing and Q&A

Transformation of EDAP | Focal One®

Our Next Chapter as FocalTherics™

Ryan Rhodes, CEO

FocalTherics™ 4

Focal Therapy

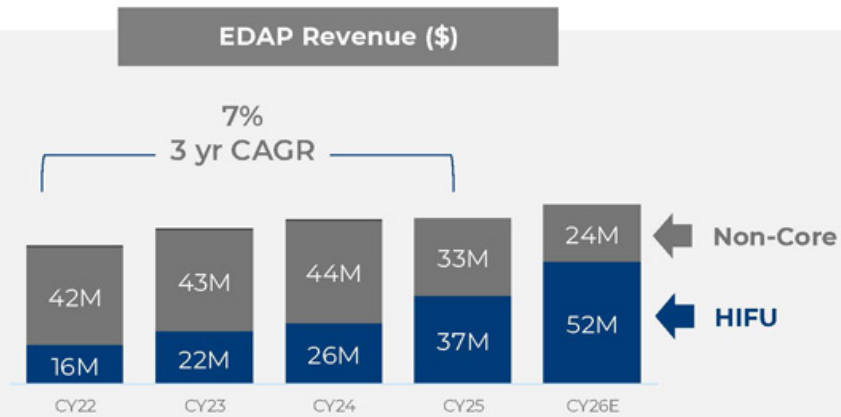
Therapeutics

FocalTherics™

We are Transforming into a High-Growth Pure-Play,
Robotic Focal Therapy Company with a Leading Position in
Both Large and Growing Markets

Commitment to Focal Therapy

Focusing on Accelerating Our Growth Engine

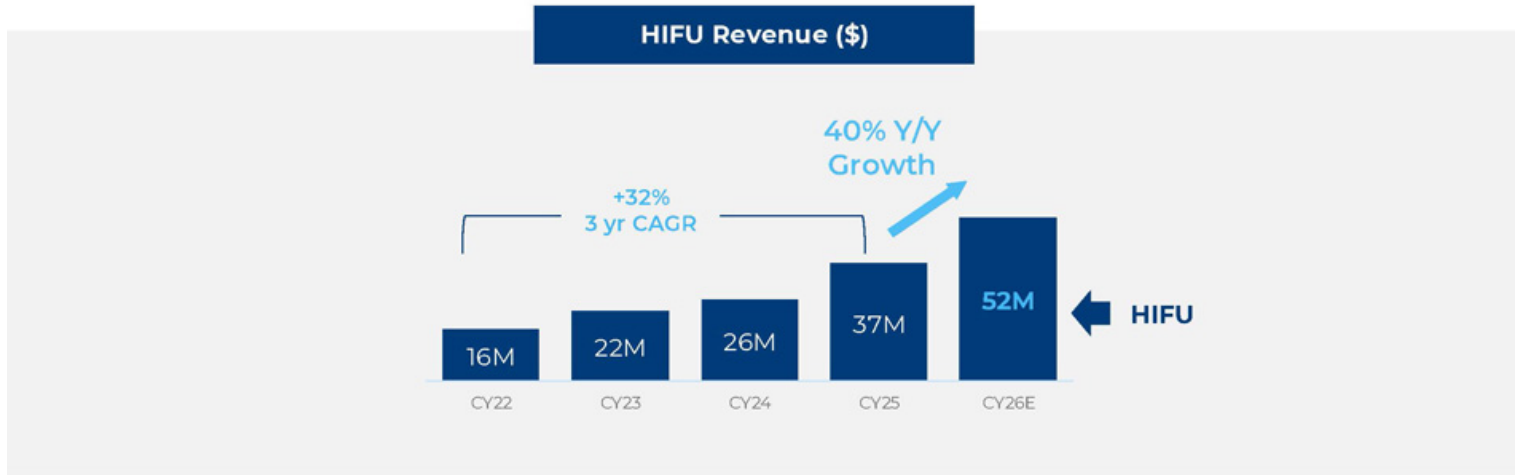


Moving Non-Core ESWL and Distribution Business to Discontinued Operations as of Q2 CY26

Note: CY26E = Midpoint of CY26 Guidance Range

Commitment to Focal Therapy

Focusing on Accelerating Our Growth Engine



Note: CY26E = Midpoint of CY26 Guidance Range

FocalTherics™



Global Leader in Therapeutic Ultrasound

Redefining the Treatment of Cancer and
Benign Disease through Organ Sparing,
Function Preserving Focal Therapy



FocalTherics™ 8

Driving Growth Across Three Strategic Pillars

Scaling Commercial
Execution in
Prostate Cancer

Expanding our Market
Opportunity with Added
Indications on the
Focal One Platform

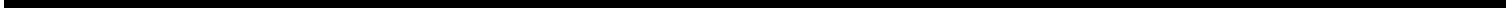
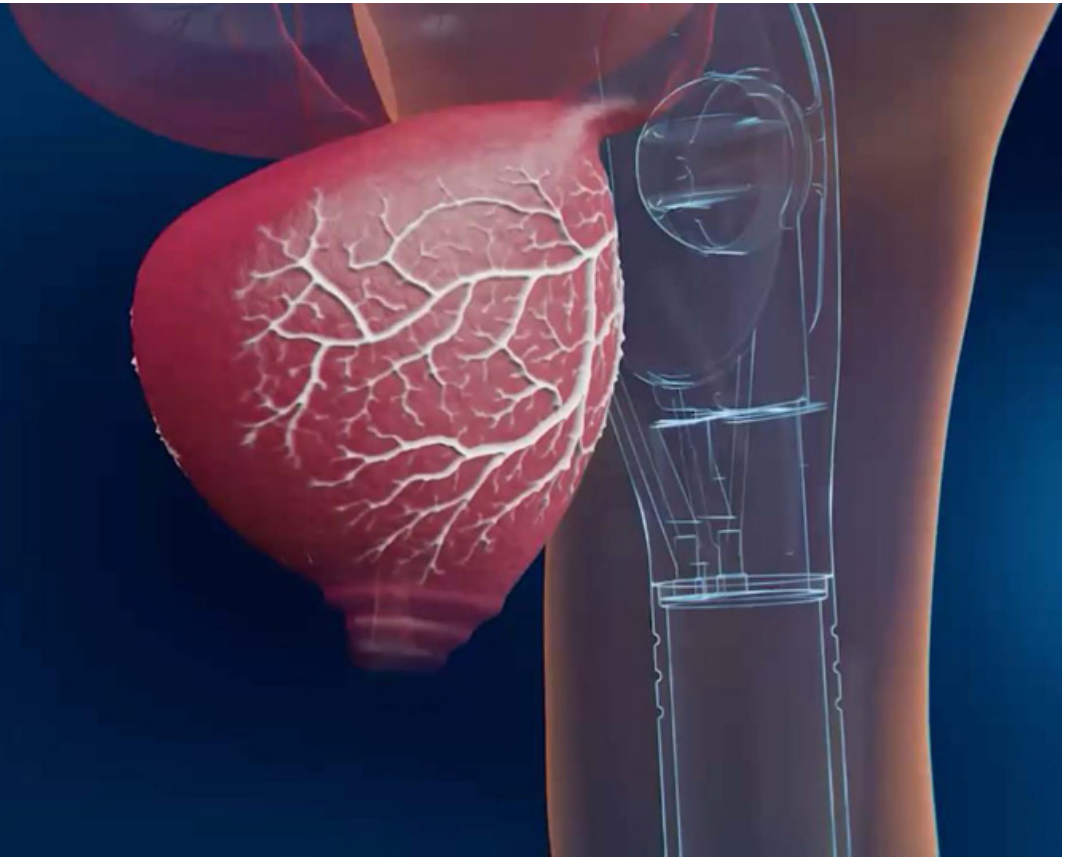
Advancing
Technological
Innovation in HIFU
and Beyond

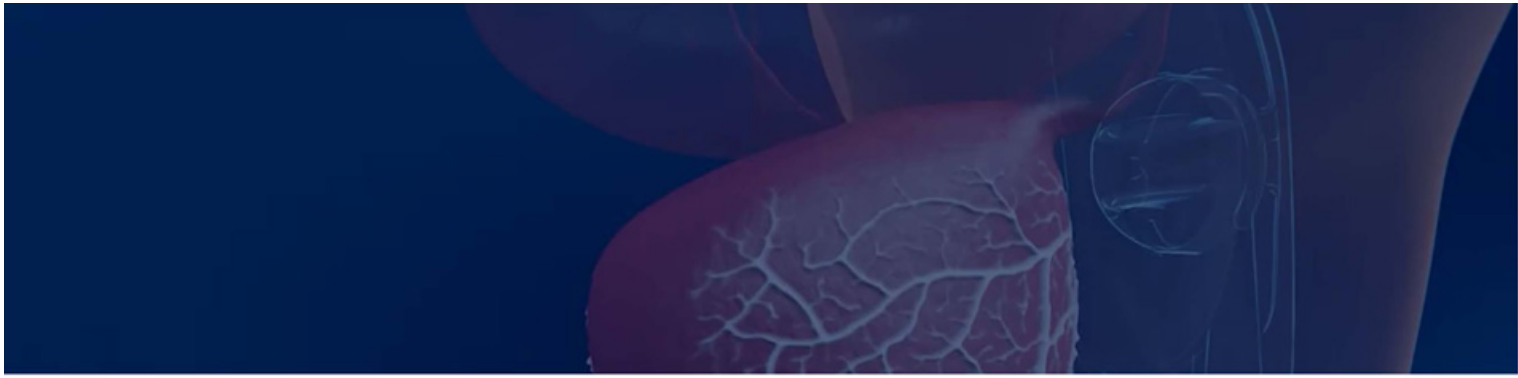
Non-Invasive

No Surgery

No Cutting

No Radiation





Advanced Imaging

**High-Intensity Focused
Ultrasound (HIFU)**

**Precise Robotic
Energy Delivery**



**Organ Sparing,
Function Preserving**



Defining, Building, and Leading the Category of Robotic Focal Therapy



FocalTherics™ 12

Driving Commercial Success in Current Markets

Prostate Cancer

Prostate Cancer is the Most Common Cancer Among Men¹

>1.4 Million²

New Cases Diagnosed Annually, Globally

>330,000

New Cases Diagnosed Annually in the U.S.

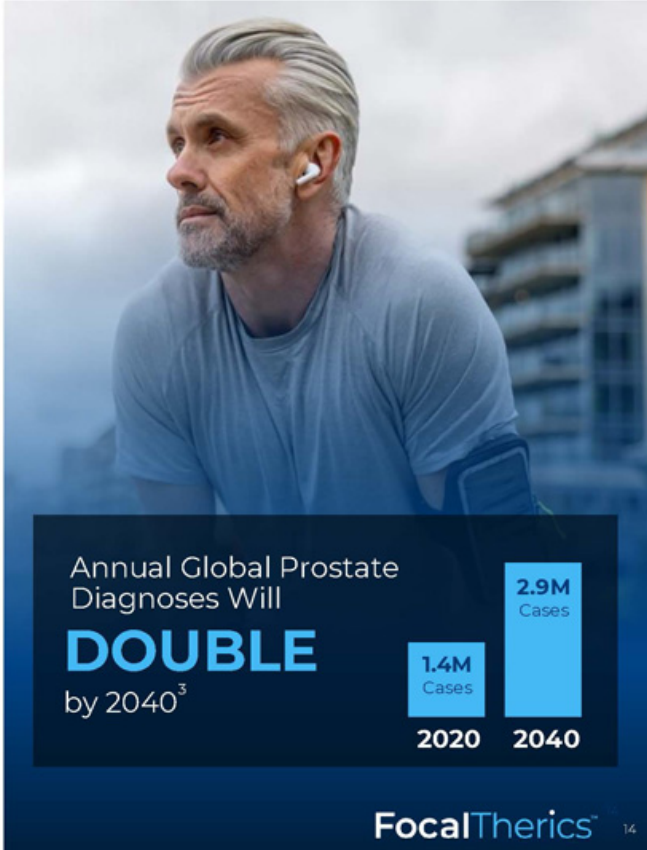
>3.5 Million

Men Living with Prostate Cancer in the U.S.

[1] 2026 estimates from the American Cancer Society (www.cancer.org)

[2] 2022 estimates from the World Health Organization (www.who.int)

[3] James N. Tannock & N'Dow J et al. The Lancet Commission on prostate cancer: planning for the surge in cases. The Lancet. 2024; 403, 1683-1722



Annual Global Prostate Diagnoses Will

DOUBLE

by 2040³

Year	Cases
2020	1.4M
2040	2.9M

FocalTherics™ 14

The Shift from Radical Treatment to Focal Therapy

Surgery is Still Surgery...

Open Surgery



Laparoscopic Surgery



Robotic Surgery



Radiation is still Radiation...

XRT Radiation



IMRT Radiation



SBRT Radiation

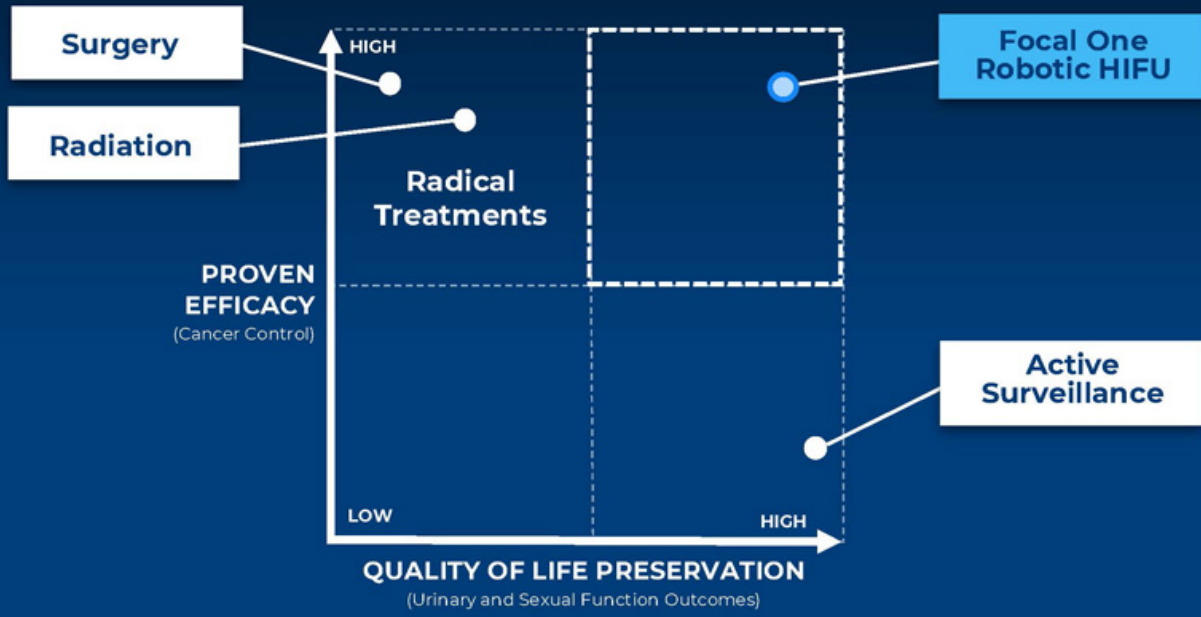


**Robotic Focal
HIFU Ablation**

The Prostate Cancer Patient's Dilemma

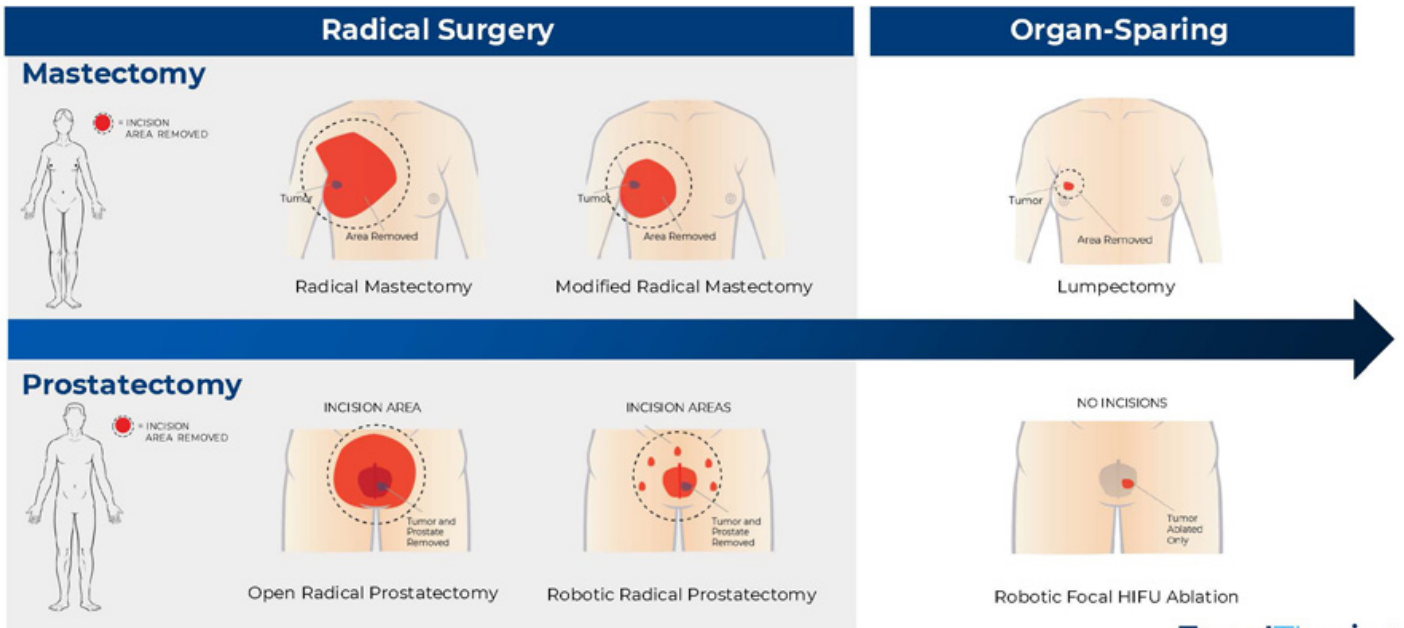


Prostate Cancer Patient Value Equation



From Radical To Organ-Sparing Treatments

The Evolution of Breast and Prostate Cancer Surgery



The Large Gap Between No Treatment and Radical Treatment



Previously, There Have Been **No Options**, Other Than Active Surveillance or Radical Treatments, **to Address Intermediate Risk Patients**

The Large Gap Between No Treatment and Radical Treatment

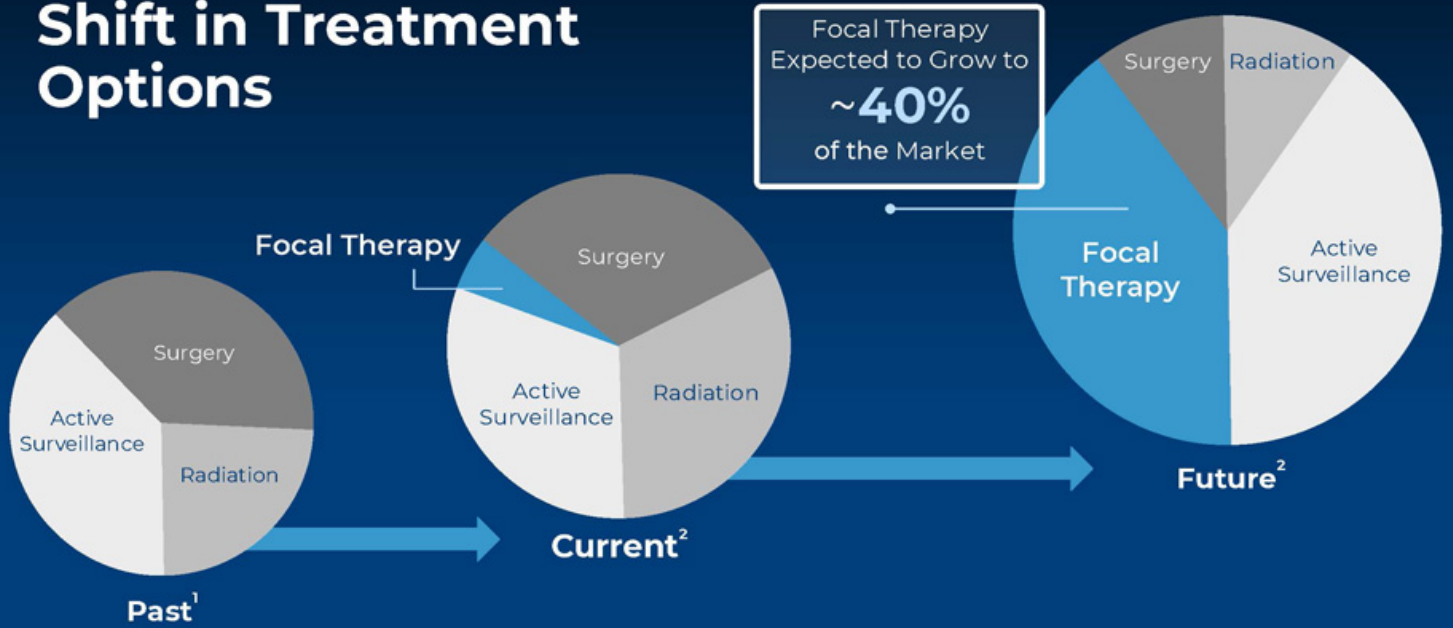


Low and Intermediate Risk Patients **Represent a >\$4B TAM²**

¹ Fletcher, Sean A et al, "Contemporary national trends in prostate cancer risk profile at diagnosis." Prostate cancer and prostatic diseases vol. 23,1 (2020): 81-87. doi:10.1038/s41391-019-0157-y

² Company Data on File

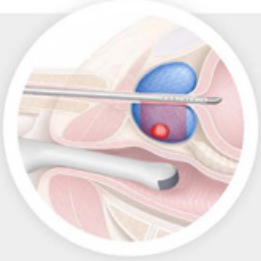
Emerging Paradigm Shift in Treatment Options



[1] As of 2013, Chen et al. National trends in the management of localized prostate cancer: A population-based analysis 2004-2013. Prostate.
[2] Company Data on File

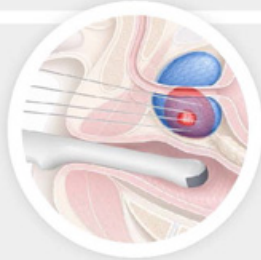
Focal One Transrectal HIFU

Offers Superior Access, Precision, and Tissue Preservation



Transurethral

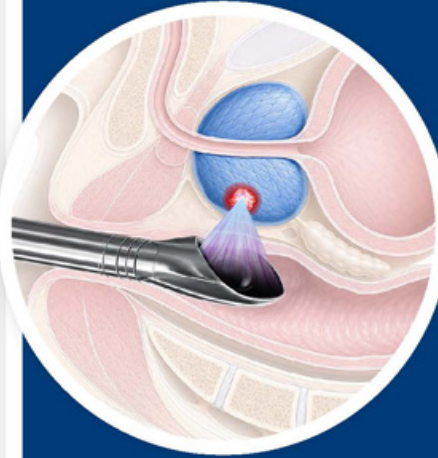
- × Requires MRI Suite and 2nd Physician
- × Non-Focused Energy
- × Bleeding from Urethra and Tissue Damage



Transperineal
(Needle-Based)

- × Punctures Through Perineum
- × Manual Placement and Positioning
- × Bleeding from Tissue Damage

Focal One Transrectal HIFU

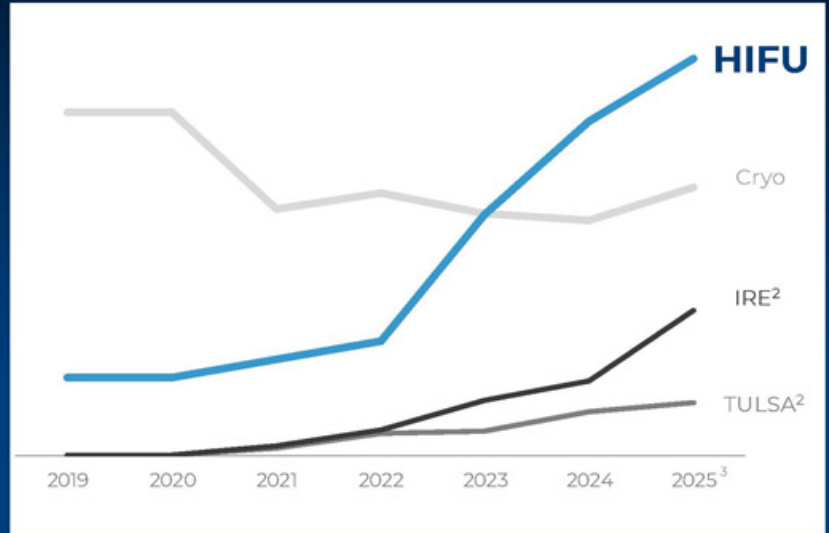


- ✓ Single Urologist
- ✓ Precise Focused Ultrasound
- ✓ Targeted Robotic Energy Delivery
- ✓ Closest Proximity To Target Tissue
- ✓ Urethra Sparing
- ✓ No Bleeding

HIFU

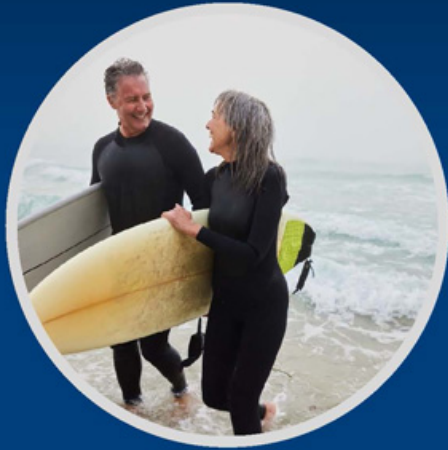
Fastest Growing
Focal Therapy Treatment¹

#1 Ablation Technology
for Prostate Cancer



¹ Based on Medicare claims utilization data published by CMS in connection with the Hospital Outpatient Prospective Payment System (HOPPS) Final Rules for CY 2021-CY 2026.
² IRE and TULSA treatment volumes may include procedures other than prostate cancer treatment, as applicable billing codes are not historically prostate-specific.
³ Company Data on File

Clinical Evidence Supports and Favors Focal One Robotic HIFU



Landmark Studies Demonstrate Positive Clinical Outcomes Supporting Focal One HIFU Therapy

Prospective Comparative

HIFI¹
European Urology

HIFU vs Radical Prostatectomy

HIFU Demonstrated High Cancer Control and Superior Continence and Erectile Function Preservation

Prospective Salvage

HIFI-2²
European Urology Oncology

HIFU in Salvage Post Radiation

HIFU Demonstrated High Cancer Control. 71% ADT-free Survival at 30 Months

Long-Term Retrospective

CGRD³
Int. Urology and Nephrology

HIFU vs Radiation

HIFU Demonstrated Higher Survival at 10 Years versus Radiation

RCT

FARP⁴
Presented at AUA 2025

Focal Ablation vs Radical Prostatectomy

Focal Ablation Demonstrated Equivalent Cancer Control

RCT

HIFUSA⁵
Presented at AFU 2025

HIFU vs Active Surveillance

HIFU Demonstrated Superior Progression-Free Survival compared to Active Surveillance

[1] Piousard G et al. "Whole-gland or Subtotal High-Intensity Focused Ultrasound Versus Radical Prostatectomy: The Prospective, Non-Inferiority, Nonrandomized, HIFI Trial." *European Urology*, November 2024. DOI: 10.1016/j.eururo.2024.11.006 [2] Piousard G et al. "HIFI-2: Prospective nationwide study across 12 centers in France, 533 patients. ADT-free survival 71% at 30 months." *European Urology Oncology*, 2025. [3] Yeh HT et al. "10-year oncological outcomes of EBRT versus HIFU for stage II prostate cancer: a multicenter Chang Gung Research Database [CGRD] study with inverse-probability-of-treatment-weighting (IPTW) analysis." *International Urology and Nephrology*, 2025. DOI: 10.1007/s11255-025-04805-7. [4] Baco E et al. "Final 3-year outcome of Focal Ablation versus Radical Prostatectomy (FARP) Randomized Controlled Trial." Presented at 120th AUA Annual Meeting, April 27, 2025. NCT03669652. [5] S. Crouzet et al. "Résultat préliminaire de l'étude randomisée HIFUSA." *Progrès en Urologie - PMC*, Volume 35, Issue 7, Supplement, 2025. Pages S14-S15, ISSN 1761-676X.

Largest Prospective Comparative Multicenter Study in the Treatment of Prostate Cancer

3,328 Patients

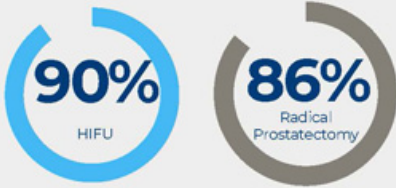
46 Centers

80+ Urologists

1

Cancer Control Primary Endpoint

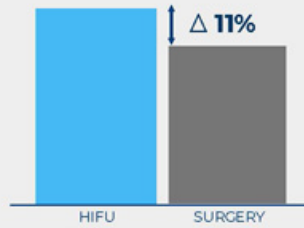
Patients Free from Salvage Treatment at 30 Months



2

Maintain Urinary Control Secondary Endpoint

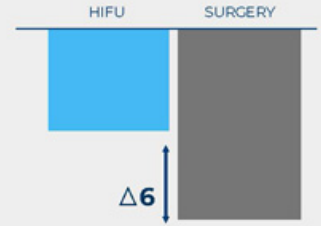
Pad-Free Continence at 12 Months



3

Preserve Erectile Function Secondary Endpoint

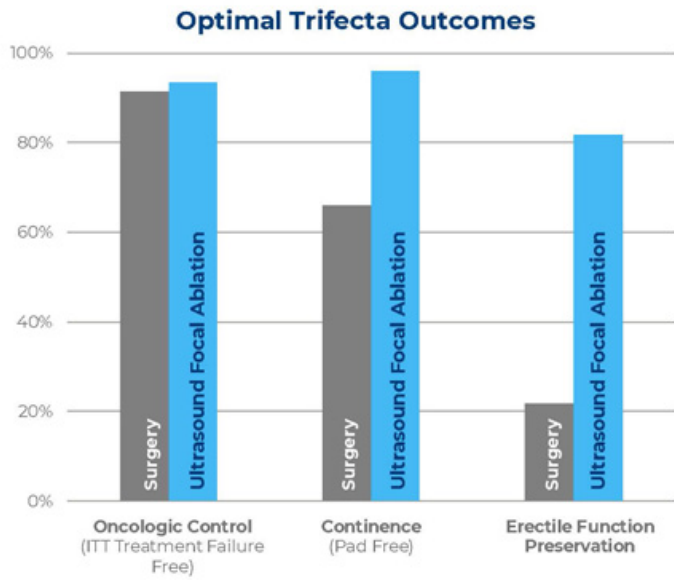
Decrease from Baseline at 12 Months



[1] Ploussard et al. "Whole-gland or Subtotal High-Intensity Focused Ultrasound Versus Radical Prostatectomy: The Prospective, Noninferiority, Nonrandomized HIFI Trial." *European urology* vol. 875 (2025): 526-533. doi:10.1016/j.euro.2024.11.006

FARP: Focal Ablation vs Radical Prostatectomy

Level 1 Evidence from RCT Validates HIFI Study Outcomes^{1,2}



213 Patients
Randomized Controlled Trial

Equivalent Oncologic Control
at 3 years (93.5% TFF vs 91.5%)

Superior Functional Outcomes

25% of Patients
Refused Radical Prostatectomy
after Randomization and Chose
Focal Ablation

[1] Baco et al. Final three-year oncological results of a randomized clinical trial FARP comparing Focal Ablation and Radical Prostatectomy in patients with unilateral clinically-significant prostate cancer. Journal of Urology [Internet]. 2025 May 12;155(5):e714. [2] Baco et al. Focal Ablation Versus Radical Prostatectomy for Intermediate-Risk Prostate Cancer: Interim Analysis of a Randomized Controlled Trial. The Journal of Urology. Vol. 206, No. 3S, Supplement, Sunday, September 12, 2021.

Growing Global Adoption of Focal One Robotic HIFU



Focal One is the Leading Focal Therapy Technology

Strong Adoption by the Highest Ranked Prostate Cancer Hospitals in the US



Best Hospitals for Urology

70%
7 Out of 10



SUO Approved Programs

66%
23 Out of 35



NCCN Member Institutions

58%
19 Out of 33



FOCAL ONE ADOPTION ACCELERATING At Major European Hospitals

**41 Focal One Systems as of Dec. 31, 2025
254 Focal One Treatment Clinical Sites**

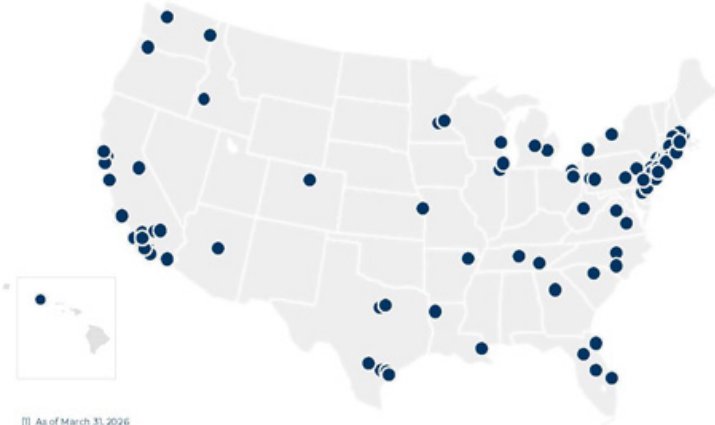


FocalTherics has the Most Established And Growing Global Commercial Adoption of any Focal Therapy Company

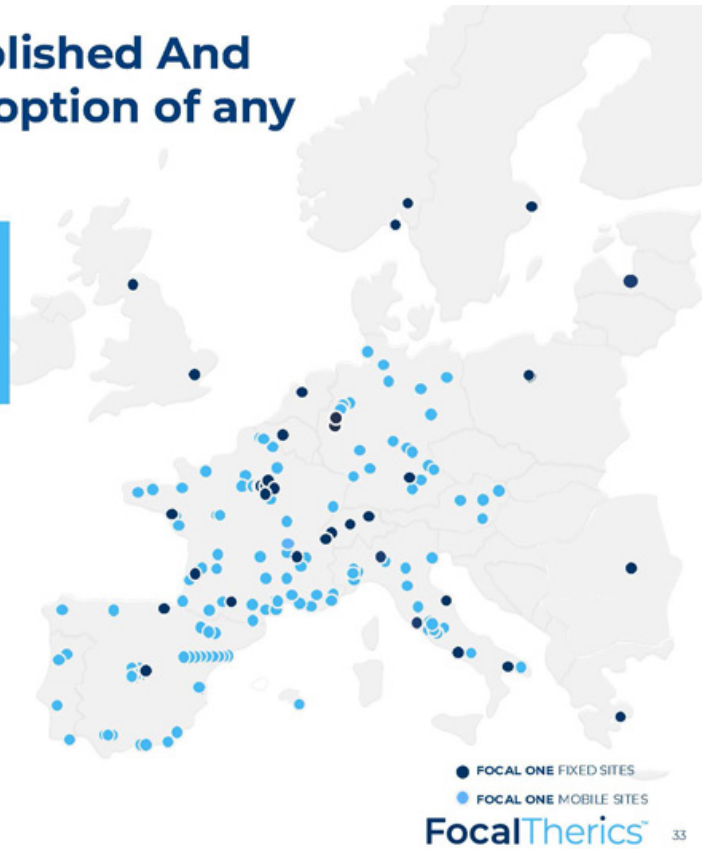
175+

Installed Base¹

Full Spectrum of
Academic Centers, Large
Community Hospitals &
Regional Centers



[1] As of March 31, 2026



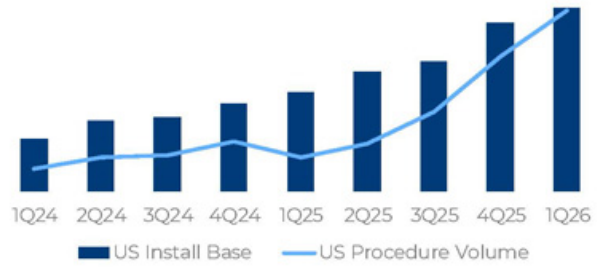
● FOCAL ONE FIXED SITES
● FOCAL ONE MOBILE SITES
FocalTherics 33

Consistent Execution Driving Durable Growth

U.S. Market



[1] As of March 31, 2026



91
Installed Base¹

53%
Procedure Volume Growth¹

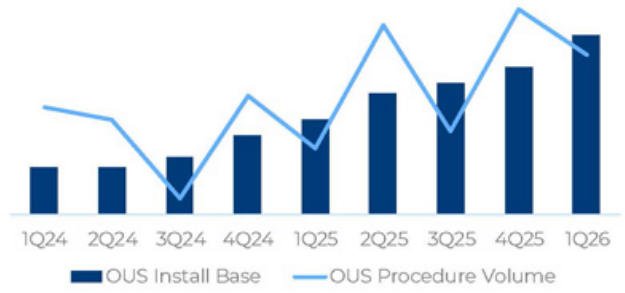
- Expanding Installed Base at Community Hospitals and Major Health Systems, Including Opportunities for Multi-System Sites
- Growing Physician Adoption Through Education, Training, and Clinical Evidence
- Driving Patient Demand for a Non-Invasive, Effective, Function Preserving Treatment Option

Sharpened Commercial Strategy in Key Markets

O.U.S Market



[1] As of March 31, 2026



84
Installed Base¹

30%
Procedure Volume Growth¹

- Direct Commercial Model in Select Markets (UK, Nordic Countries, etc.)
- Reimbursement Established in France from HIFI Study
- Converting a Legacy Mobile System Service Model to Capital Sales
- Initial Entry into India and LatAm Countries
- Early Launch in Endometriosis Driving Multi-Specialty Sales

FocalTherics™ 35

Executing Disciplined Commercial Strategy for Scalable Growth

Targeting

Account Activation

- Expand Installed Base through Sales to Greenfield High-Volume Centers
- Prioritize Accounts with Multi-System and Multi-Urologist Opportunities

<10%

Penetration into Initial Target Market Leaves Substantial Runway

Building

Program Building

- Drive Increased Utilization with Physician Training, Education & Clinical Evidence
- Develop Robust Patient Pipeline through Dedicated Hospital Marketing and Program Support

53%

YoY Procedure Growth in Q1 2026

Scaling

Program Independence

- Transition Sites to Clinically Autonomous Programs
- Reduce Reliance on Clinical Staffing as Programs Mature

70%

U.S. Procedures YTD Required No Clinical Application Support



STRONG REIMBURSEMENT
**Creates Favorable
Environment
for Growth**

1. **Cat. 1 CPT® Code at APC Level 6**
2. **Favorable Physician Payment**
3. **Growing Coverage**

Based on CMS Hospital Outpatient Prospective Payment System Final Rule

Hospital Outpatient Medicare Payment

Procedure	CPT® Code	2026 Payment	
Prostate Brachytherapy	55875	\$5,478	
Cryo Ablation	55873	\$9,671	
HIFU	55880	\$9,671	+4.3%
Laparoscopic/Robotic Prostatectomy	55866	\$10,860	

Favorable Physician Payment

Procedure	CPT® Code	Work RVU (2026)	Physician Payment (Medicare - 2026)
MRI Transurethral Ultrasound Ablation	55882	11.21	\$530
Prostate Brachytherapy	55875	13.12	\$693
Cryo	55873	13.26	\$692
Irreversible Electroporation	55877	13.50	\$675
HIFU	55880	17.29	\$884
Laparoscopic/Robotic Prostatectomy	55866	21.90	\$1,087

Expanding Patient Access

Medicare Coverage: Automatic for All Patients Nationwide

National and Local Plans may Provide Individual Payment According to their Coverage Policies and/or Local Arrangements

Existing and Upcoming Positive Clinical Evidence will Provide Broader and Expanded Coverage



Clinical Expansion of our Focal One Platform

BPH and Endometriosis

Benign Prostatic Hyperplasia (BPH) Market

100+ Million¹

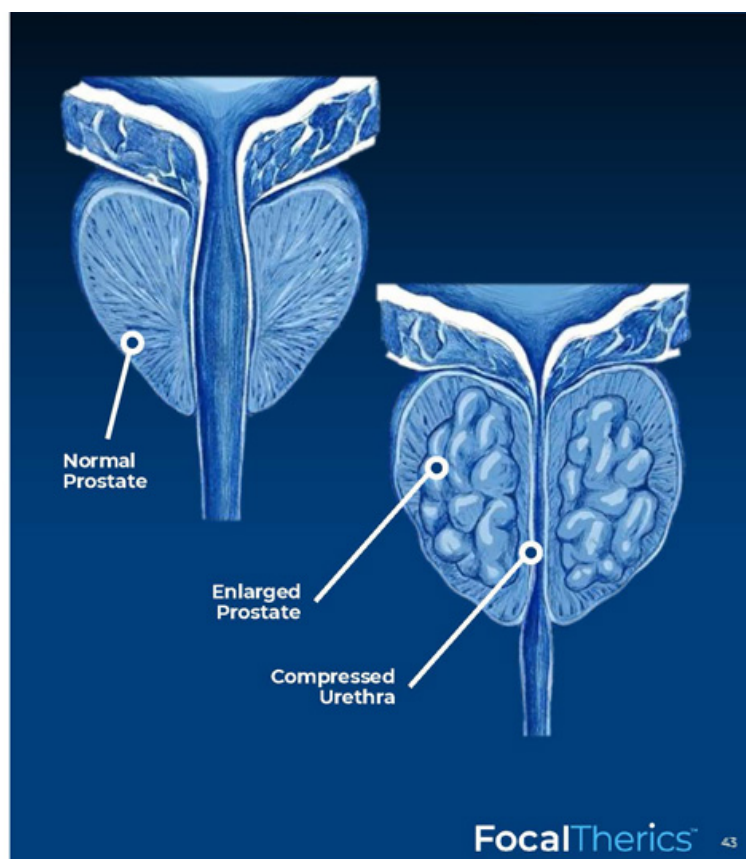
Men Living with BPH Globally

13+ Million¹

New Cases Diagnosed Annually, Globally

600,000+²

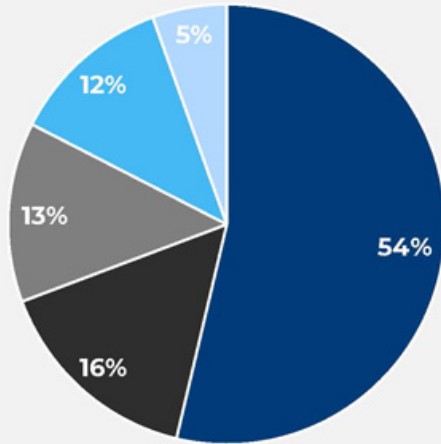
New Cases Diagnosed in the U.S.



^[1] Chen X, Yang S, He Z, Chen Z, Tang X, Lin Y, Huang Y, Hou J, Wei X. Comprehensive analysis of the global, regional, and national burden of benign prostatic hyperplasia from 1990 to 2021. Sci Rep. 2025 Feb 15;15(2):5644. doi: 10.1038/s41598-025-90229-3. PMID: 39954408; PMCID: PMC11331013.

^[2] Urologic Diseases in America, 2024. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 2024.

BPH Treatment is a Highly Fragmented Market



■ TURP ■ Aquablation ■ Urolift ■ HoLEP ■ Rezum

Focal One will be the **ONLY Non-Invasive, Non-Surgical** Focal Therapy Solution

Market share calculated as each procedure's share of 283,935 reported US BPH procedures in 2025 across TURP, Aquablation, Urolift, HoLEP, and Rezum.
Source: ProstateAtlas analysis of 2025 US BPH procedure volumes.
Procedure-volume proxy only; does not represent total BPH care, as ~95.9% of diagnosed US BPH patients were managed without procedural intervention in 2025.

BPH Indication Expansion Pipeline



A BPH Solution Designed to Meet Patient Priorities

Non-Invasive

No Bleeding

No Foreign Body

No Quality-of-Life Tradeoffs



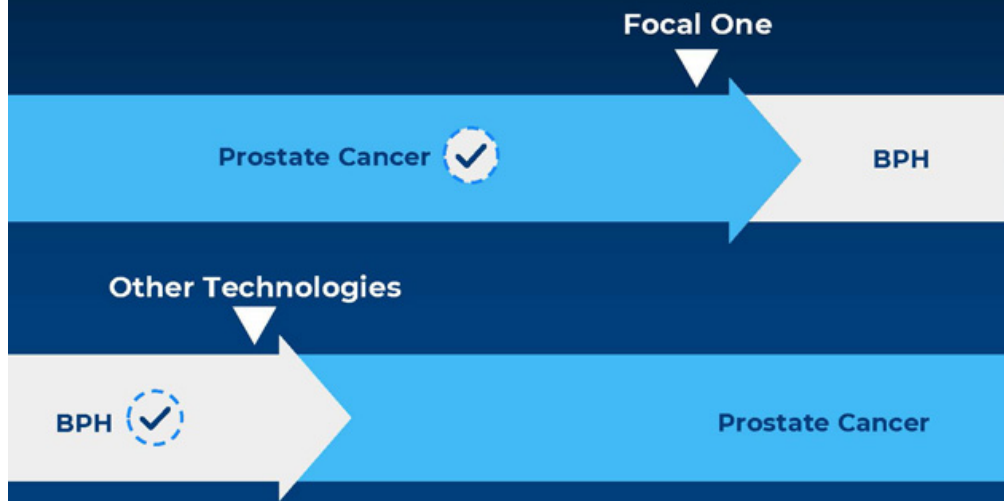
Particularly Compelling for the Growing Number of
BPH Patients on Anti-Coagulation Medication
who are at Risk of Bleeding Complications

Ideally Suited to Capture Significant Portion of BPH Market



- **Same** Focal One Platform
- **Same** Installed Base
- **Same** Urology Call Point
- **Same** Physicians & Staff

Straightforward Pathway to Additional Prostate Indications



Payment and Coding

Freedom to Operate

CPT Category 3 Code
(Transrectal HIFU Treatment,
Specifically for BPH)

Regulatory

Enrolling Parallel
Studies

14 Patients Treated
in Latin America

Deep Infiltrating Endometriosis (DIE)

38M

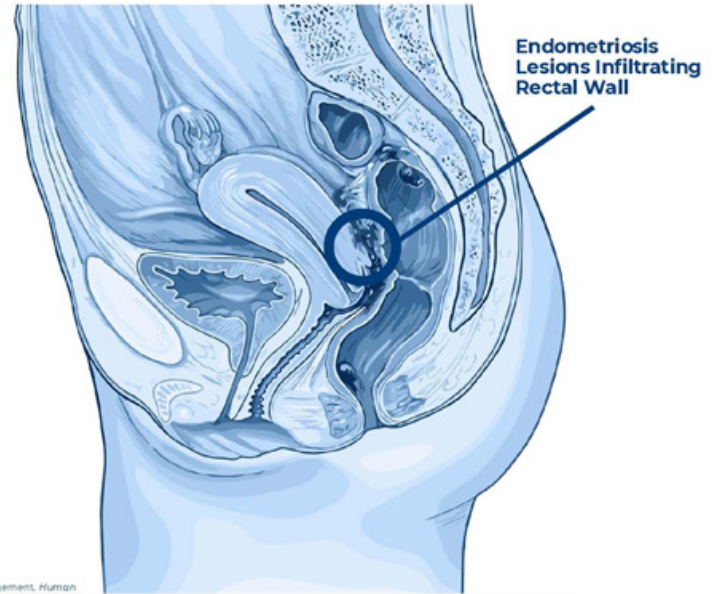
Women Living with Deep Infiltrating Endometriosis Globally^{1,2,3,4}

783,000+

Patients Diagnosed with Deep Rectal Endometriosis Globally^{1,2,3,4}

225,000+

Patients Diagnosed with Deep Rectal Endometriosis in U.S.^{1,2,3,4}

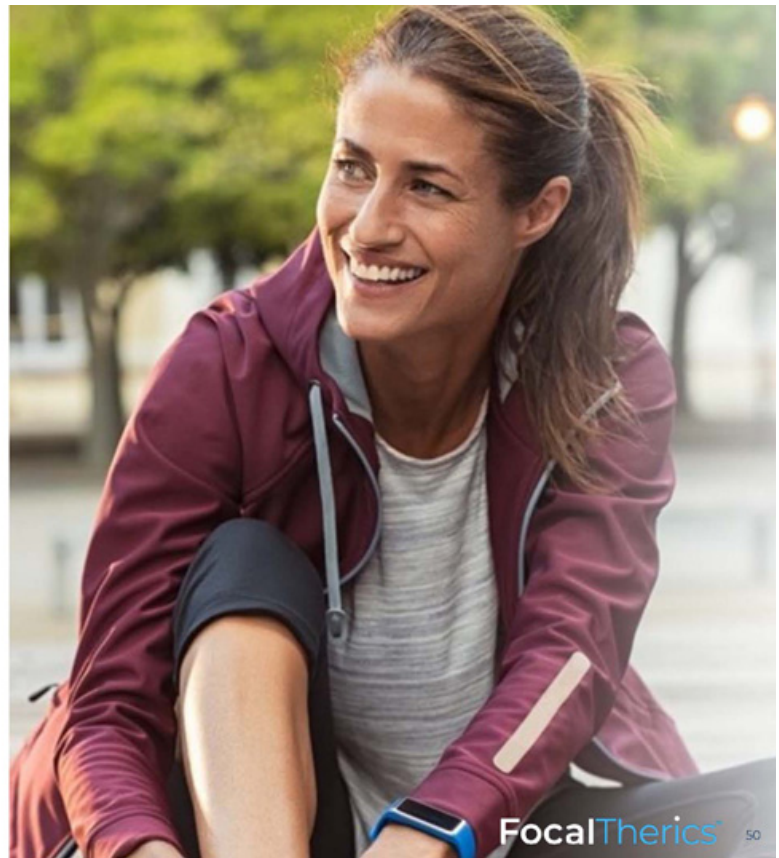


[1] Abrão MS, Petraglia F, Falcone T, Keckstein J, Osuga Y, Chapron C. Deep endometriosis infiltrating the recto-sigmoid: critical factors to consider before management. *Human Reproduction Update*, 2015; 21(3):329-339. [2] Wenwei L, Huiyan Feng, Qinglan Ye. Factors contributing to the delayed diagnosis of endometriosis — a systematic review and meta-analysis. *Frontiers in Medicine*, 2025; doi:10.3389/fmed.2025.1576490. [3] Agarwal SK, Chapron C, Giudice LC, et al. Clinical diagnosis of endometriosis: a call to action; underdiagnosis estimated at up to 60%. *DeBo Corte L et al. 2020; cited in scoping review 2024.* [4] United Nations, Department of Economic and Social Affairs, Population Division, *World Population Prospects 2024. Women aged 15-49 by country, 2024 mid-year estimates.* [5] Vecellini D, et al. Surgery versus hormonal therapy for deep endometriosis: hormonal treatment is ineffective or not tolerated in ~30% of women. *Minerva Ginecol*, 2016; PMID 27544308.

Deep Infiltrating Endometriosis (DIE)

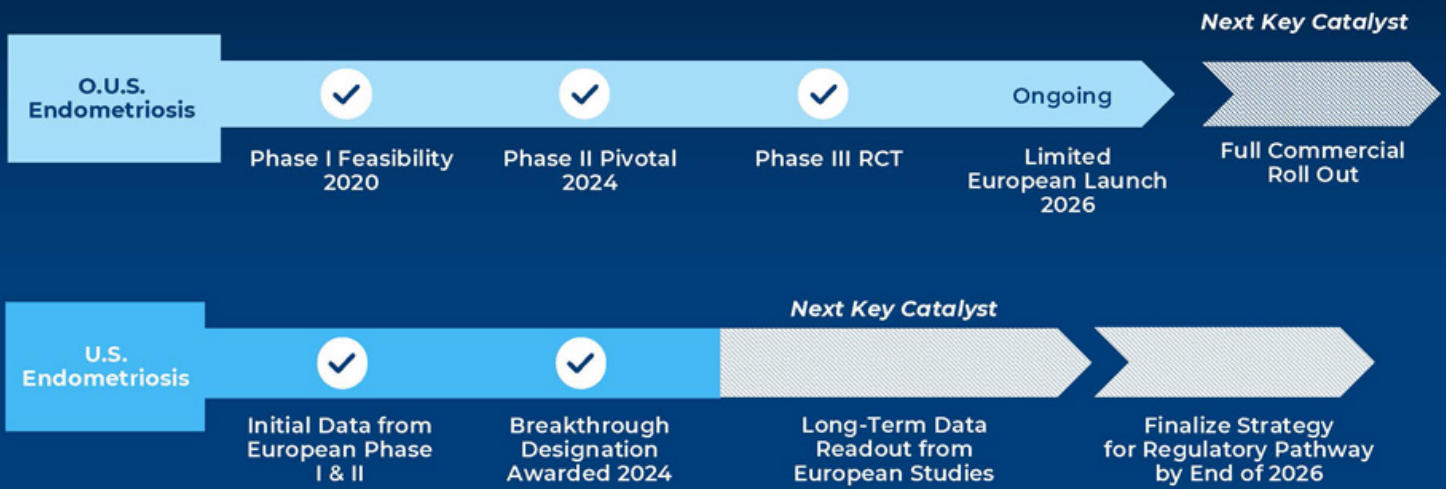
Characterized by Lesions that Penetrate >5mm Below the Peritoneal Surface, Invading Surrounding Structures like the Bowel, Bladder, and Rectum.

Current Treatment Options are Lacking and Limited to Hormonal and/or Surgical Management. When Offered the Choice, **91% of Women Prefer Non-Surgical Options¹**



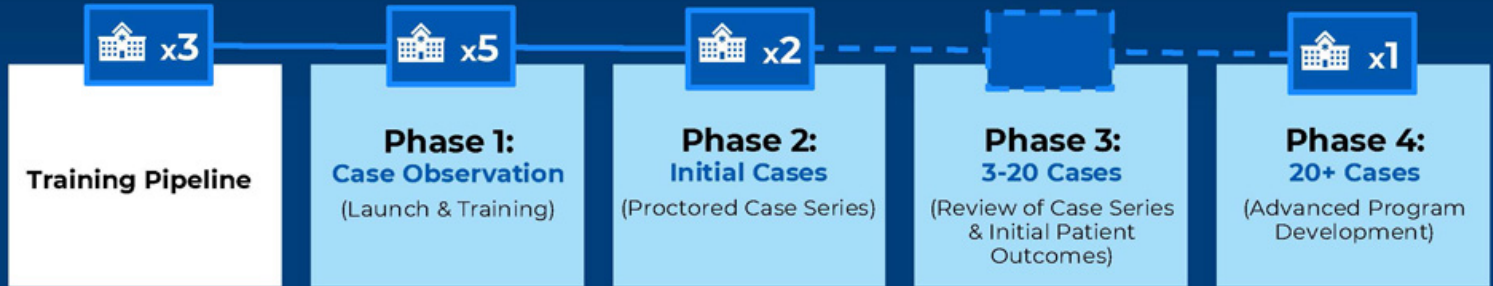
[1] Vecellini P, et al. Surgery versus hormonal therapy for deep endometriosis: hormonal treatment is ineffective or not tolerated in ~30% of women. Minerva Ginecol, 2016; PMID 27544308.

Endometriosis Indication Expansion Pipeline

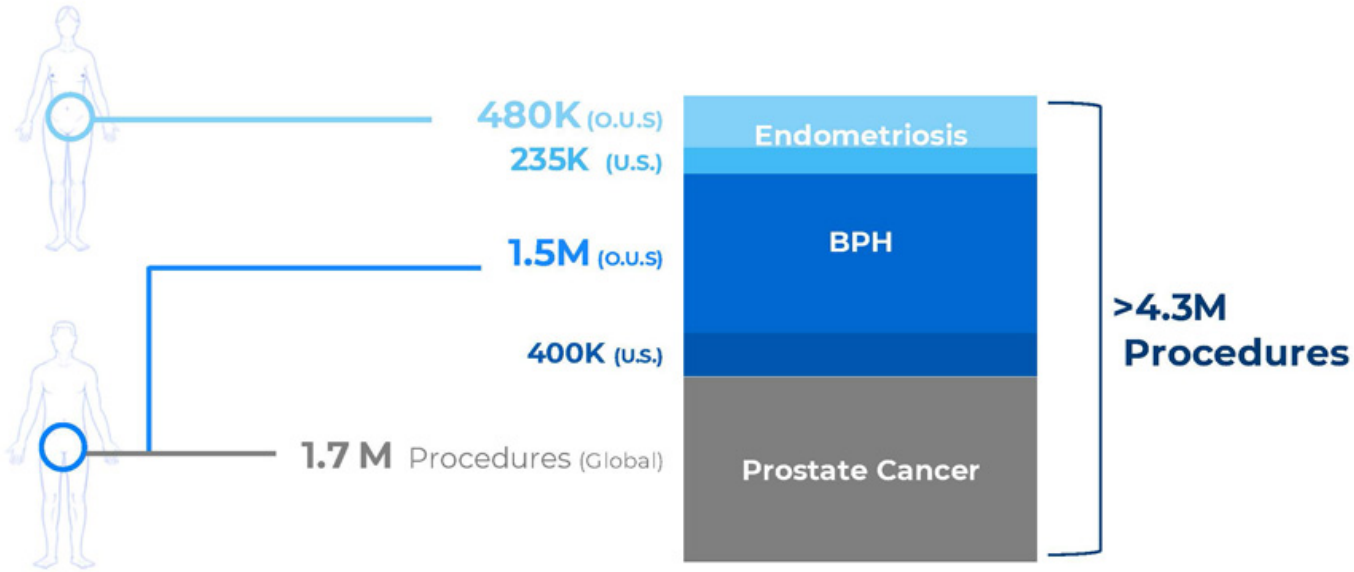


Phased Launch Program Establishes Framework for Broad Commercial Rollout

Goal to end 2026 with Several Active Reference Centers with Influential Thought Leaders



Focal One Platform Expansion Opportunity Represents a TAM of **4.3M+¹ Procedures** and **\$10B+ Revenue**



¹ Management Estimates; data on file.

Behfar Ehdai, MD, MPH
Memorial Sloan Kettering Cancer Center



Focal Therapy for Prostate Cancer and Urologic Oncology: A Paradigm Shift in Treatment

Behfar Ehdaie, MD, MPH
Associate Member

Urology Service, Department of Surgery
Department of Epidemiology and Biostatistics

Memorial Sloan Kettering
New York, NY

Hello Dr. Ehdaie,

Thank you for getting back to me.

I say this every time I see you ->Thank you. While on long lines for the mens' rooms at sporting events or theaters, I "pee" on command quickly and efficiently like a teenager. I think my friends and husband are jealous. Listening to other guys my age (gay and straight) I think I have a better sex life than they do. I am never short of amazed about how my quality of life, while different, has remained so positive [REDACTED]

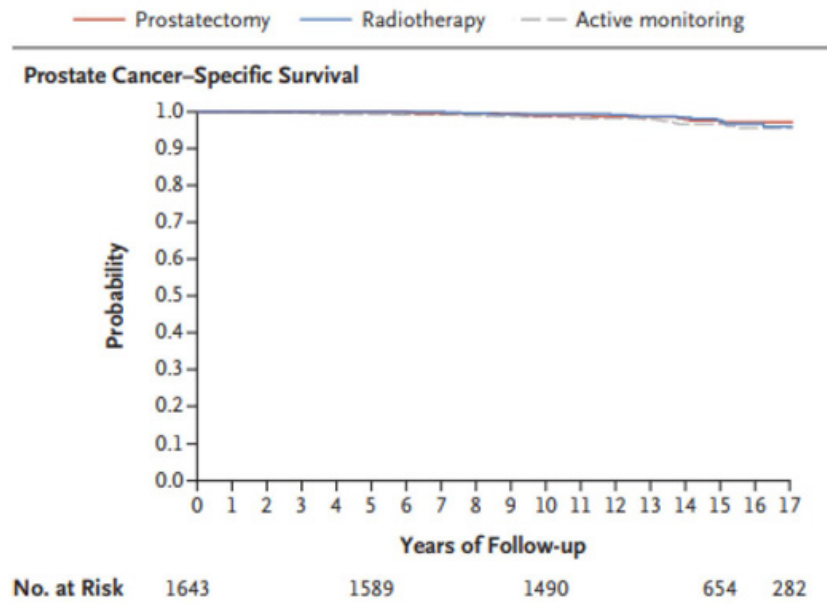
[REDACTED] .. BUT I faired sooooo much better than other guys, [REDACTED]

[REDACTED] You remain a man who truly made my life better.

No need to reply - you are a busy man.

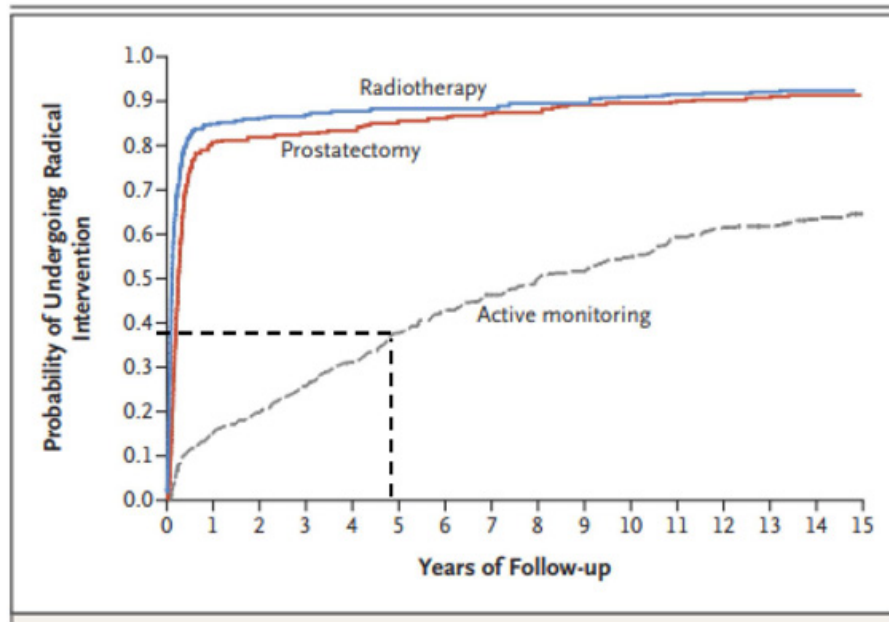
See you in a few months.
[REDACTED]

Overall Prostate Cancer Survival In All Men In The PROTECT Trial: 2.7% At 15 Years



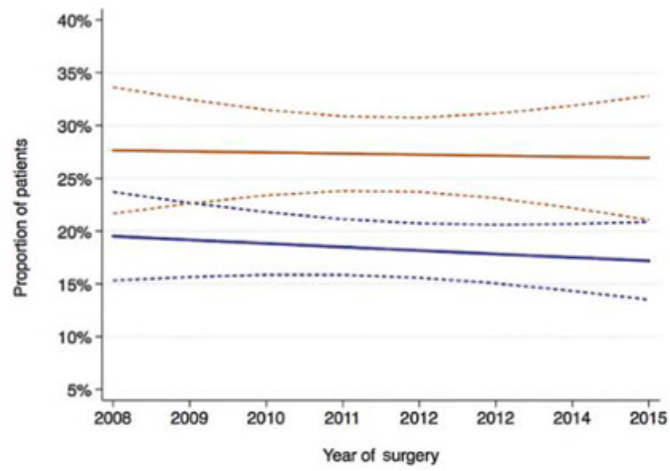
[Hamdy, 2023]

Approximately 40% Of Men Randomized To Active Monitoring Underwent Radical Prostatectomy Or Radiation Therapy Within 5 Years



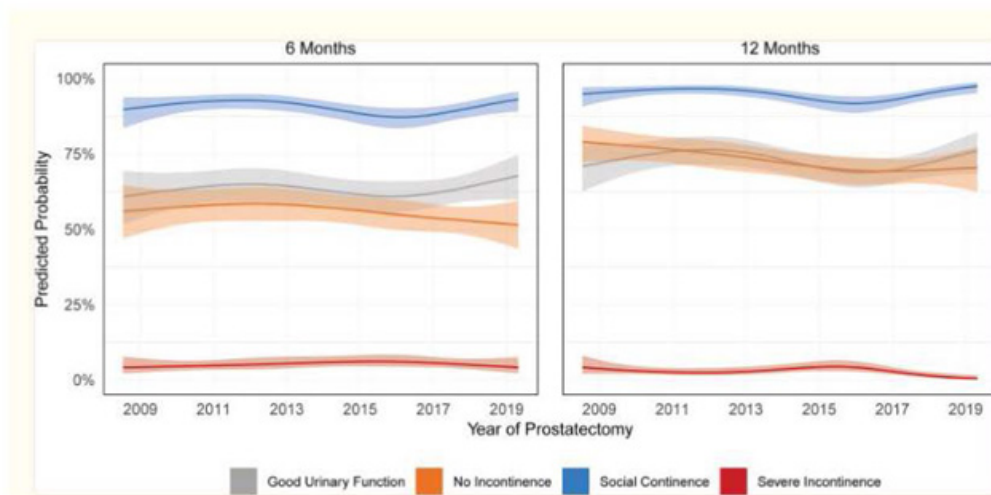
[Hamdy, 2023]

Has The Probability Of Regaining Sexual Function After Prostate Cancer Surgery Improved Over The Last Decade?



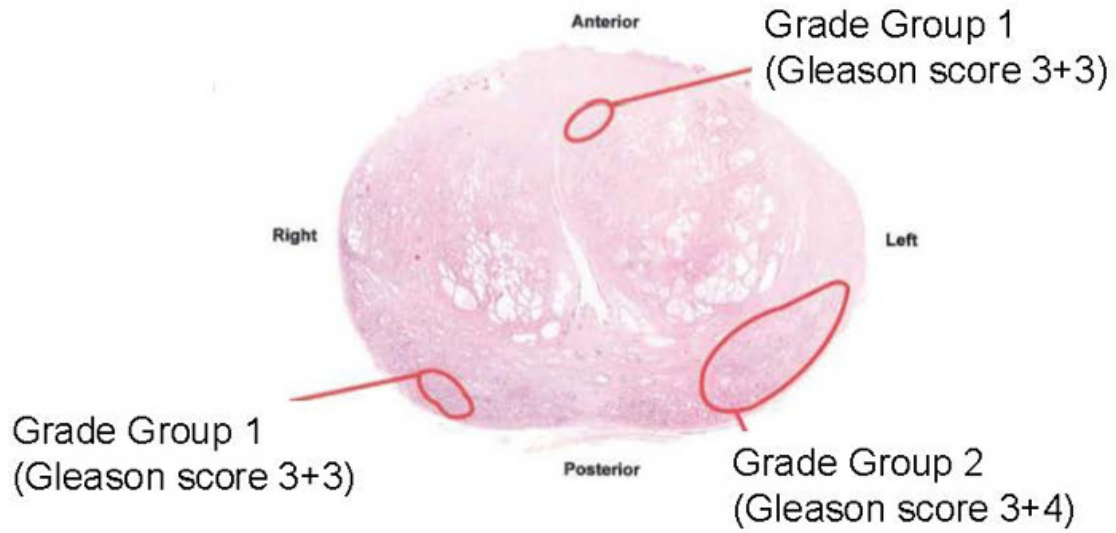
[Mulhall, 2018]

Similarly, We Have Not Observed Improvements In The Probability Of Regaining Urinary Function After Surgery



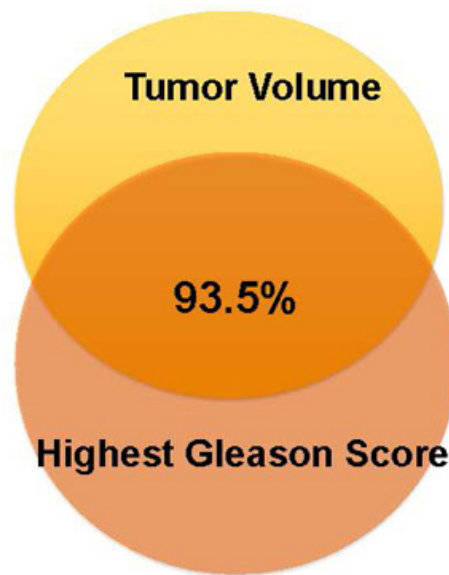
[Ehdaie, 2022]

Overcoming The Problem Of Tumor Multifocality Within The Prostate Has Been Key To The Emergence of Focal Therapy



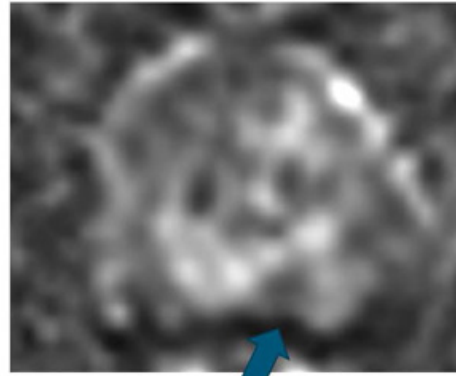
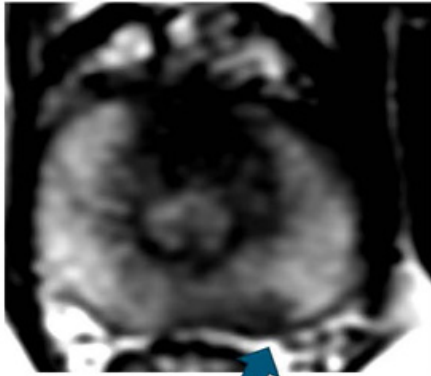
[Arora et al, 2004]

Adverse Pathologic Features, Including Highest Stage, Gleason Score, And Tumor Volume Converge To Define The *Index* Lesion



[Arora, 2004]

Multiparametric MRI Is Enabled Physicians To Detect The Index Lesion And Map The Prostate Gland



Patient Selection Criteria

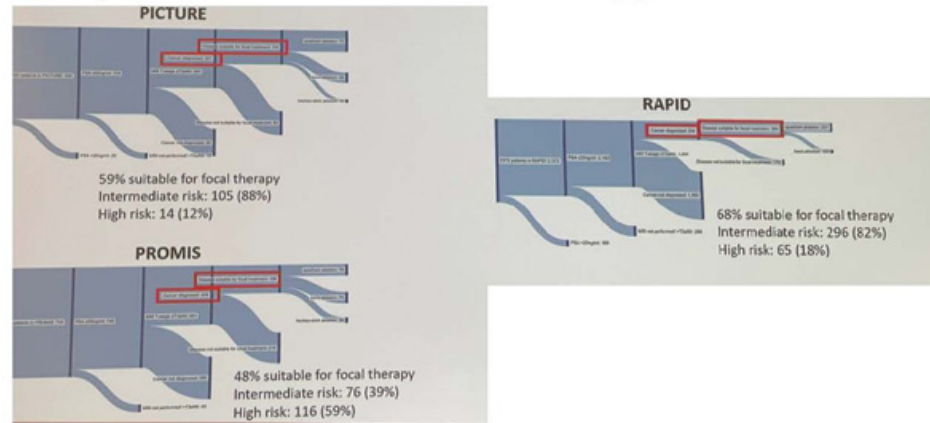
Preferred Focal Therapy Candidates:

- GG 2 or GG 3 prostate cancer in a single lesion visible on MRI
 - Concomitant GG1 prostate cancer elsewhere in the gland is allowed and observed
 - PSA \leq 20 if prostate gland size <100gm
 - No evidence of extraprostatic extension (MRI)
 - HIFU:
 - Anterior margin of treatment \leq 4cm from the rectal wall
 - No treatment plans crossing midline anterior to the urethra
-

Who Is A Candidate For Focal Therapy?

Across 3 prospective prostate cancer diagnostic and screening clinical trials in the UK (total accrual >700 patients)

- **48-68%** of patients suitable for focal therapy



Key Trends In Patient Selection Expanding Focal Therapy Eligible Patients

- A. >60% of patients in the United States with low grade prostate cancer are enrolled in active surveillance and approximately **20% of these patients** have higher grade cancer detected within 24 months
 - B. MRI targeted prostate biopsies have enabled detection of low volume 'high risk' prostate cancer in a single lesion visible on MRI
 - C. Utilization of MRI in post radiation patients have enabled **detection of recurrence earlier** and localized stage making them candidates for salvage focal treatment
-

Focal Therapy Fills An Important Treatment Gap In Prostate Cancer



- Advanced imaging and MR-targeted biopsies have improved the ability to localize disease and risk stratify prostate cancer
 - Patients are seeking an option between active surveillance and radical therapy
 - Patients are more accepting of less invasive treatments to optimize quality of life as they seek to expand their own interests instead of seeing prostate cancer as only a life or death decision
-

Where Is Focal Therapy For Prostate Cancer Today?

- Inclusion in guidelines
 - Rapid increase in scientific publications
 - Participation in focal therapy instructional courses at national meetings
-

European Association Of Urology Has Changed Their Guidelines To Include Offering Focal Therapy (HIFU/Cryo) For Prostate Cancer Outside Of Clinical Trails – Now Within Prospective Registries.

EAU Guidelines on Focal Therapy for Prostate Cancer

2022

6.1.6 General guidelines for the treatment of prostate cancer
Offer focal therapy within a clinical trial setting or well-designed prospective cohort setting.

HOW IT WAS APPLIED TO YOUR PRACTICE

Research ethics committee, legally sponsored trial only

2023

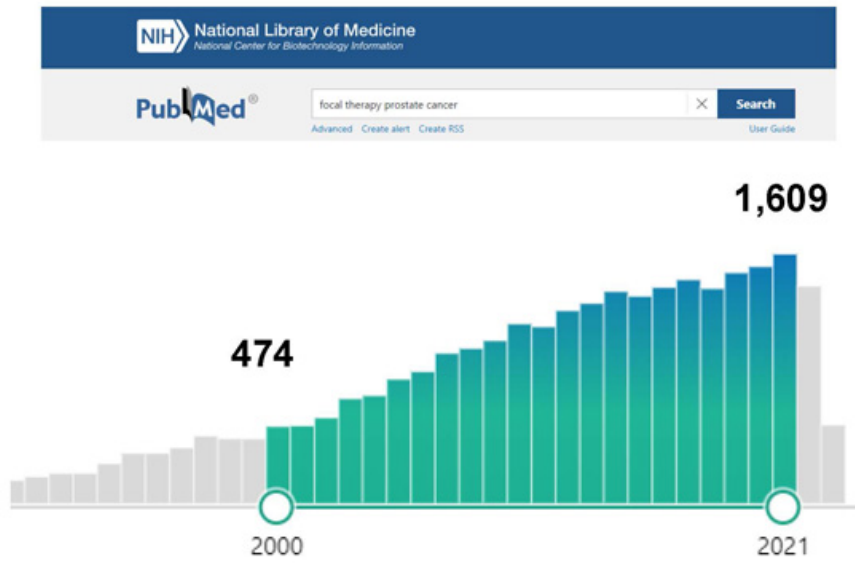
Section 6.1.5.3
Currently, focal therapy using HIFU or cryotherapy should be performed within the context of a prospective registry. All other ablative modalities should only be offered in a well-designed prospective trial setting.

6.1.6 General guidelines for the treatment of prostate cancer
Only offer focal therapy with high-intensity focused ultrasound or cryotherapy within a clinical trial or prospective registry.

HOW TO APPLY TO YOUR PRACTICE

HIFU or cryotherapy within prospective registry
ALL other modalities: research ethics committee, legally sponsored trial only

Annual Scientific Publications Have *Quadrupled* In The Last 2 Decades



American Urological Association Offered 2 Courses In Focal Therapy For Prostate Cancer And Both Sessions Were Fully Registered



My Experience With The Commercial Utilization Of The Focal One® Device

Advantages

- Leading technology among competition in efficiency and decreased treatment time per treatment
 - The robotic positioning system provides highly reproducible targeting with submillimeter accuracy and automated treatment planning thereby reducing operator variability
 - Ease of workflow: OR device without requirement of the MRI suite
 - State of the art:
 - 1) Real-time treatment modification to adjust treatment boundaries and update plans if anatomy shifts
 - 2) MRI/ultrasound fusion software to improve identifying and targeting the tumor
-



Data: Oncologic Efficacy

No evidence of clinically significant prostate cancer in the targeted area in 93% of patients at 12 months

	Whole gland 12-month biopsy	In-field (12-month biopsy)
Oncological efficacy		
No evidence of GG \geq 2	54 (89%)	57 (93%)
Biopsy Outcome		
NED	41 (67%)	57 (93%)
GG1	13 (21%)	0 (0%)
GG2	6 (9.8%)	3 (4.9%)
GG3	1 (2%)	1 (1.6%)
GG4-5	0 (0%)	0 (0%)

[Fainberg, Ehdia *Unpublished*]

Data: Quality of Life

- **Good or moderate erectile function reported in 90% of patients with or without medications at 12 months.**
- **No incontinence requiring pads reported at 12 months.**

Characteristic	N	Baseline N = 76	3-month (2-4 months) N = 56	6-month (4-9 months) N = 44	12-month (9-15 months) N = 18
MSHQ (Range 1-15; Higher Indicates Better Ejaculatory Function)	55	--	9 (4, 12)	7 (4, 10)	8 (4, 11)
IPSS (Range 0-35; Higher Indicates worse urinary symptoms)	184	6 (4, 12)	6 (3, 9)	5 (3, 10)	7 (5, 10)
IIEF (Range 1-30; Higher indicates better erectile function)	180	26 (19, 30)	20 (6, 26)	24 (7, 28)	21 (8, 29)

[Fainberg, Ehdiaie *Unpublished*]

Conclusions

- Data supports offering focal therapy as a viable treatment option for select (and growing population) of patients with prostate cancer
 - Rapid adoption in academic hospitals enables a pipeline of residents and medical students exposed to focal therapy
 - Inclusion of focal therapy in academic meetings (courses, research sessions, panels) will positively influence specialty and national guidelines
 - Focal therapy has reduced the burden of prostate cancer for patients without compromising oncologic outcomes
-

Thank you for your attention



Innovation & Advanced Technologies

Steve Annen, EVP Product Management



The Focal One Robotic HIFU Advantage

Validated by Surgeons,
Proven in Practice

Accurate Treatment
Targeting

Precision HIFU
Energy Ablation

Easy-To-Use
Workflow with
Treatment Versatility

Ongoing Commitment
to Invest in Clinician-
Driven Innovation

FocalTherics™ 76

Purpose Built for Precision Focal Therapy: Seamless Integration of Technologies

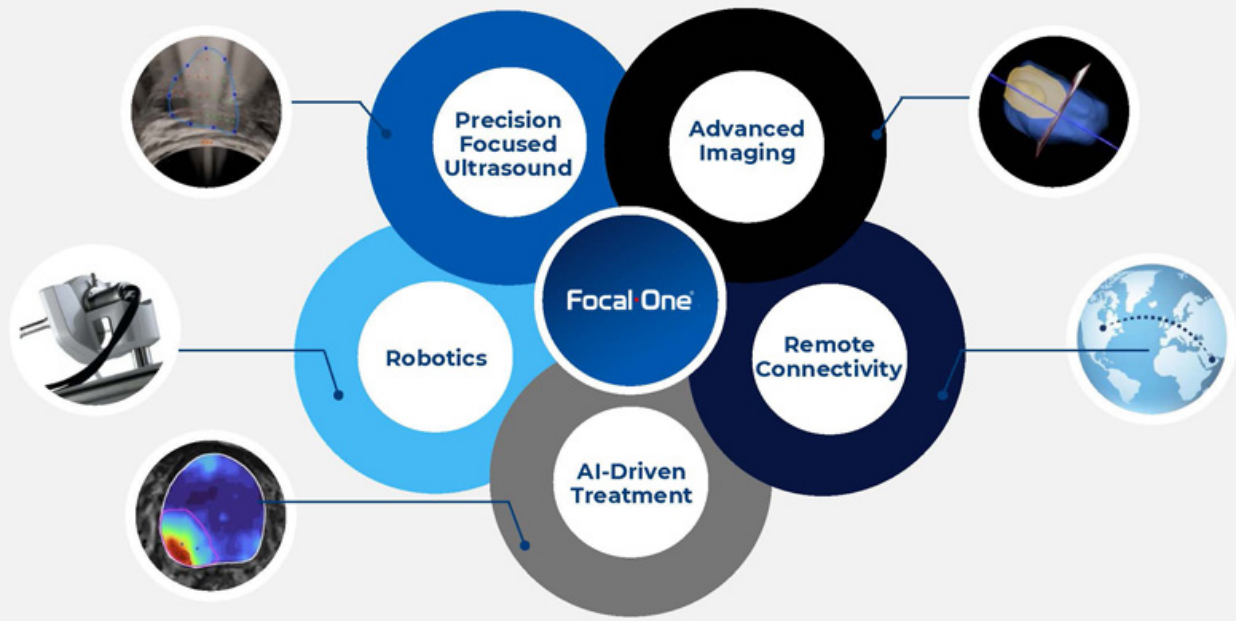
Precision
Robotics

Dynamic
Focusing
Probe

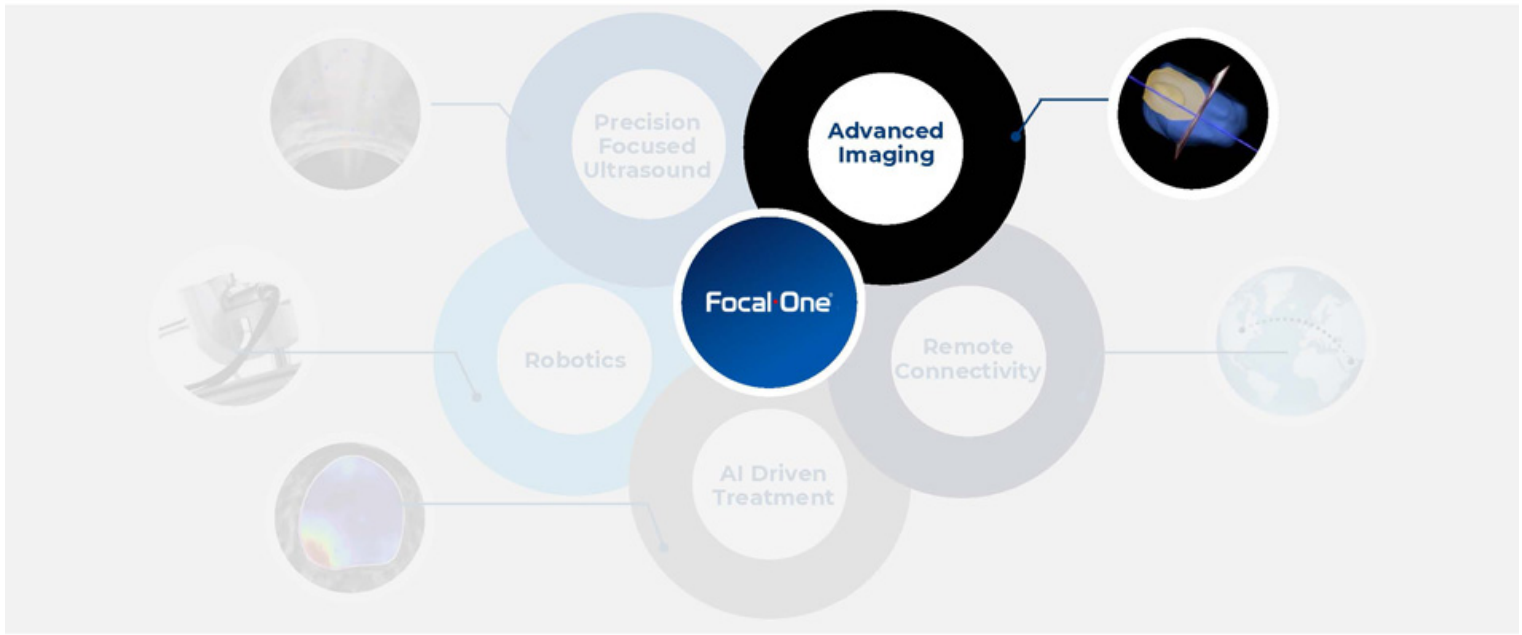
High
Resolution
Imaging

Mature
Software
Driven
Workflow

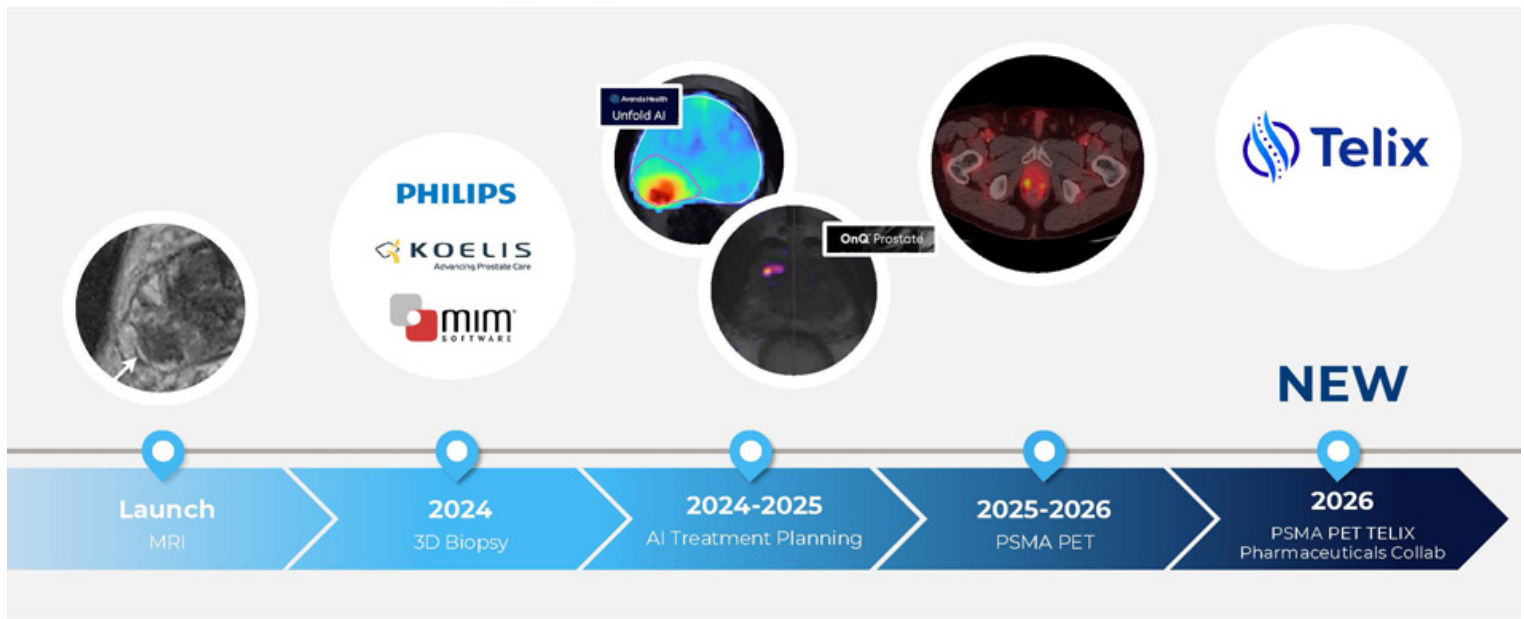
Scalable Focal One Platform Enables Simultaneous Innovation



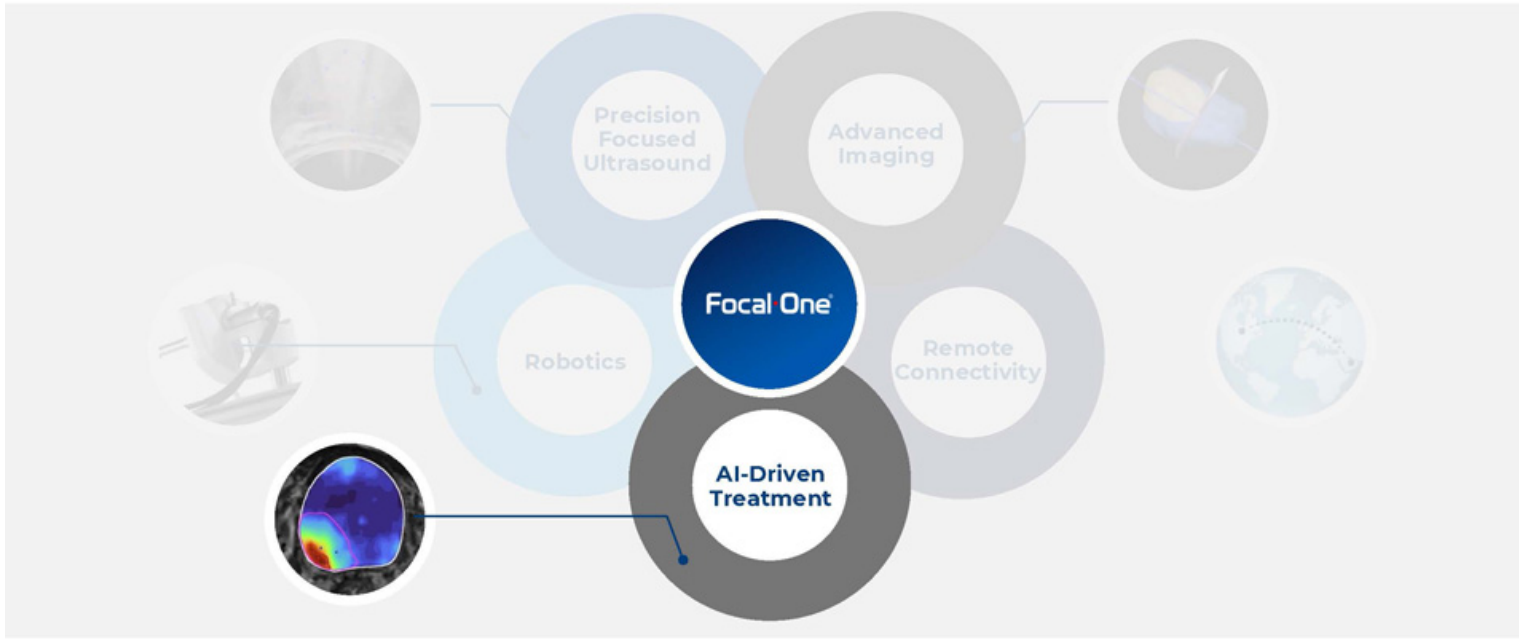
Scalable Focal One Platform Enables Simultaneous Innovation



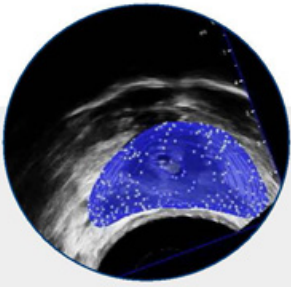
Open Platform for Advanced Imaging Driven Treatment



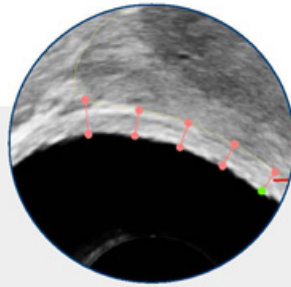
Scalable Focal One Platform Enables Simultaneous Innovation



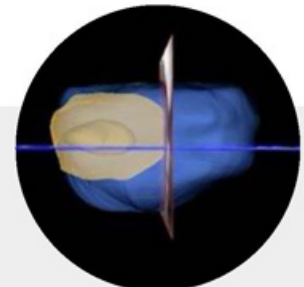
AI Integration Shaped by Clinician Feedback



Mapping of
Cancer & Critical
Structures

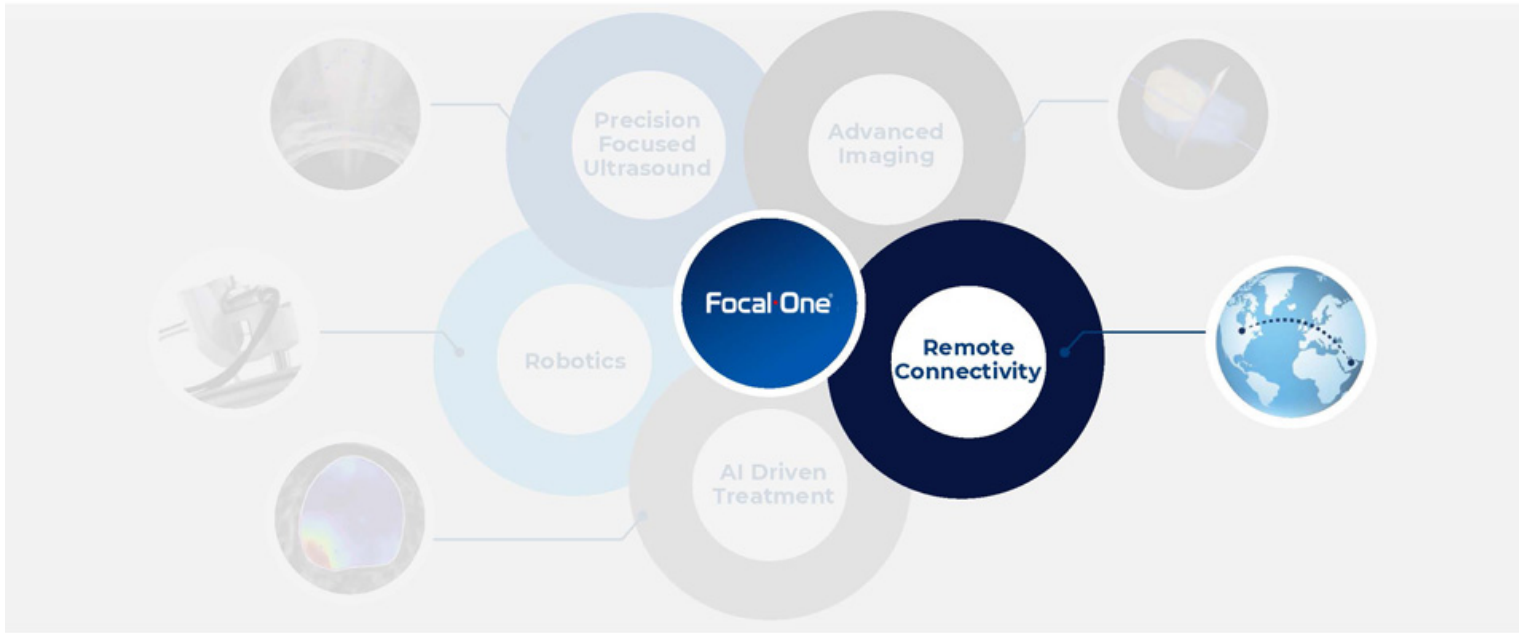


Real-Time
Monitoring of
Anatomy



Ability to
Assess Tissue
Ablation

Scalable Focal One Platform Enables Simultaneous Innovation



FocalConnect™

Focal One Uniquely Designed for
High-Fidelity Focal Therapy Telecollaboration



Completely **Integrated**
Digital Platform

Leveraging **Existing**
Hospital Networks

Broadens Patient
Access to Focal Therapy



FocalTherics™ 86


World's First Transcontinental Focal One HIFU Telecollaboration

 Cleveland Clinic



 Cleveland

7,000+ miles

 Abu Dhabi



Leveraged Hospital Network with No Delays or Interruptions

 UroToday

EUS 2025: The First-in-Human Transcontinental Telesurgery Collaboration for High-Intensity Focused Ultrasound: A New Era in Globalizing Focal Cancer Treatment for Prostate...

The first reported case of transcontinental telesurgery using High-Intensity Focused Ultrasound (HIFU) for the treatment of localized prostate cancer.

Apr 29, 2025



Dr. Oliveras

"After a while I forgot I was doing a remote surgery."

Dr. Hassen

"[Dr. Oliveras] was enabled to seamlessly perform the procedure from beginning to end without my intervention."

FocalTherics B7

FocalConnect

Enabling a New Paradigm in Focal Therapy Telecollaboration



Dual Console (Operating Room)



Across Hospital Campus



Regional Hospital Network

FocalConnect

Enabling a New Paradigm in Focal Therapy Telecollaboration



Dual Console
(Operating Room)



Across Hospital Campus



Regional Hospital
Network

FocalConnect

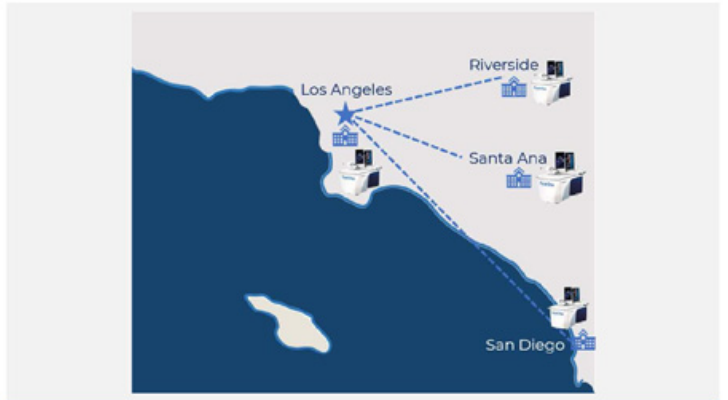
Enabling a New Paradigm in Focal Therapy Telecollaboration



Dual Console
(Operating Room)



Across Hospital Campus



Regional Hospital Networks

FocalConnect

Enabling a New Paradigm in Focal Therapy Telecollaboration



Operating Room



Across Hospital Campus



Regional Hospital Networks



Dr. Jihad Kaouk, MD
Enterprise Chair of Urology



**FocalConnect™ Accelerates the Sharing
of Best Practices in Broadening Patient
Access to Expert Care**

Cleveland
Akron



Florida



London



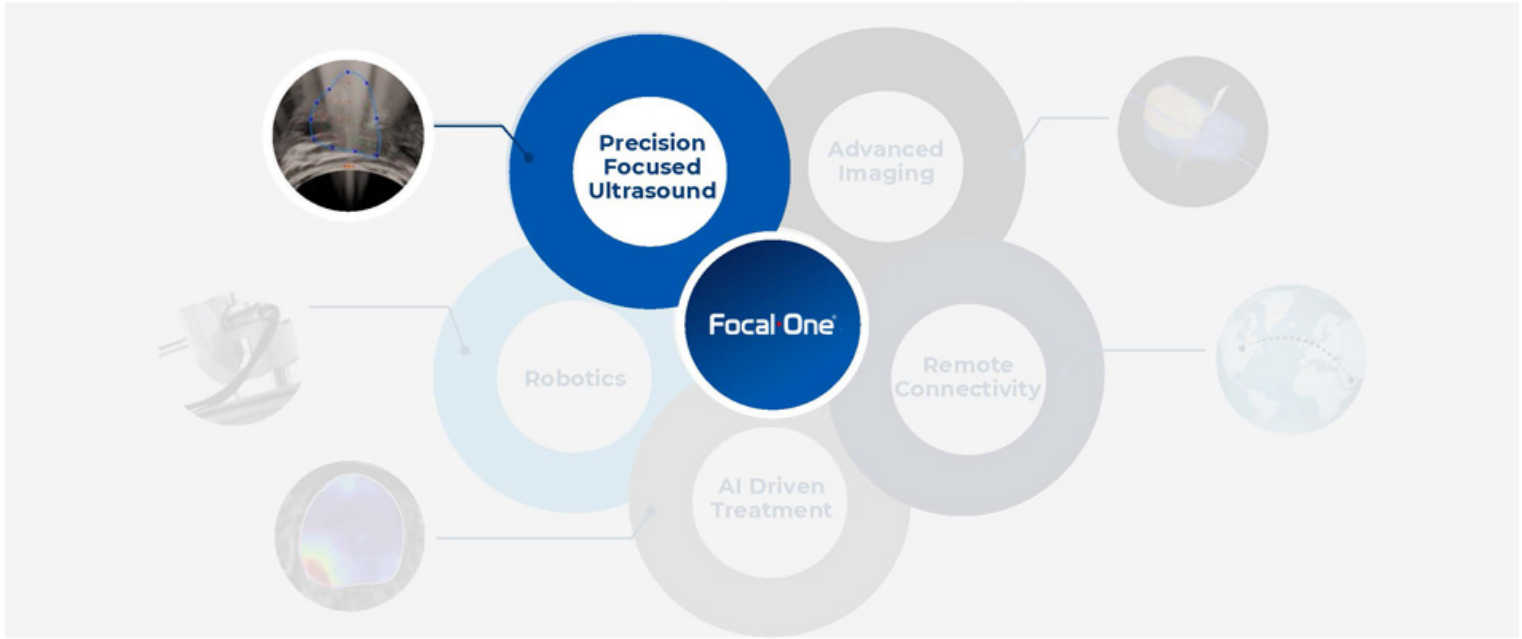
Abu Dhabi

“This innovative approach [with Focal One Robotic HIFU] not only allows us to **share expertise across Cleveland Clinic’s locations** but also **expands access to specialized care for patients**, no matter where they are.”

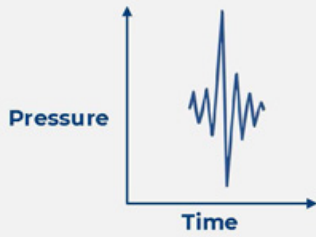
FocalConnect™

FocalTherics™ 92

Scalable Focal One Platform Enables Simultaneous Innovation



Lithotripsy

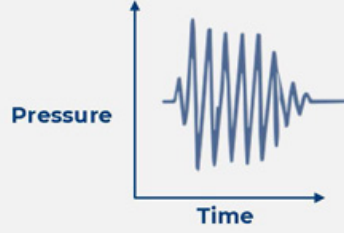


- Very Short Shock Pulse

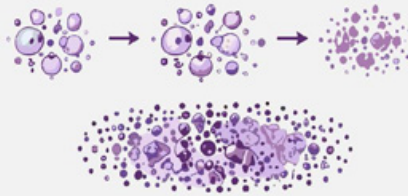


Mechanism & Tissue Effect: Mechanical Stress Causes Cracks and Fragmentations of Calcified Structures

Histotripsy

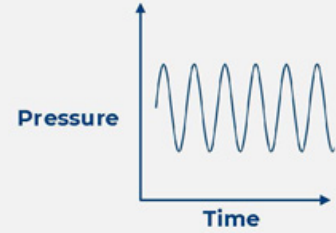


- Short Pulse Bursts

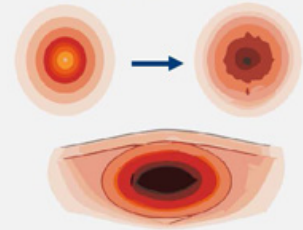


Tissue Effect: Non-Thermal Mechanical Fractionation of Tissue into Microparticles, Tissue is Liquified

HIFU



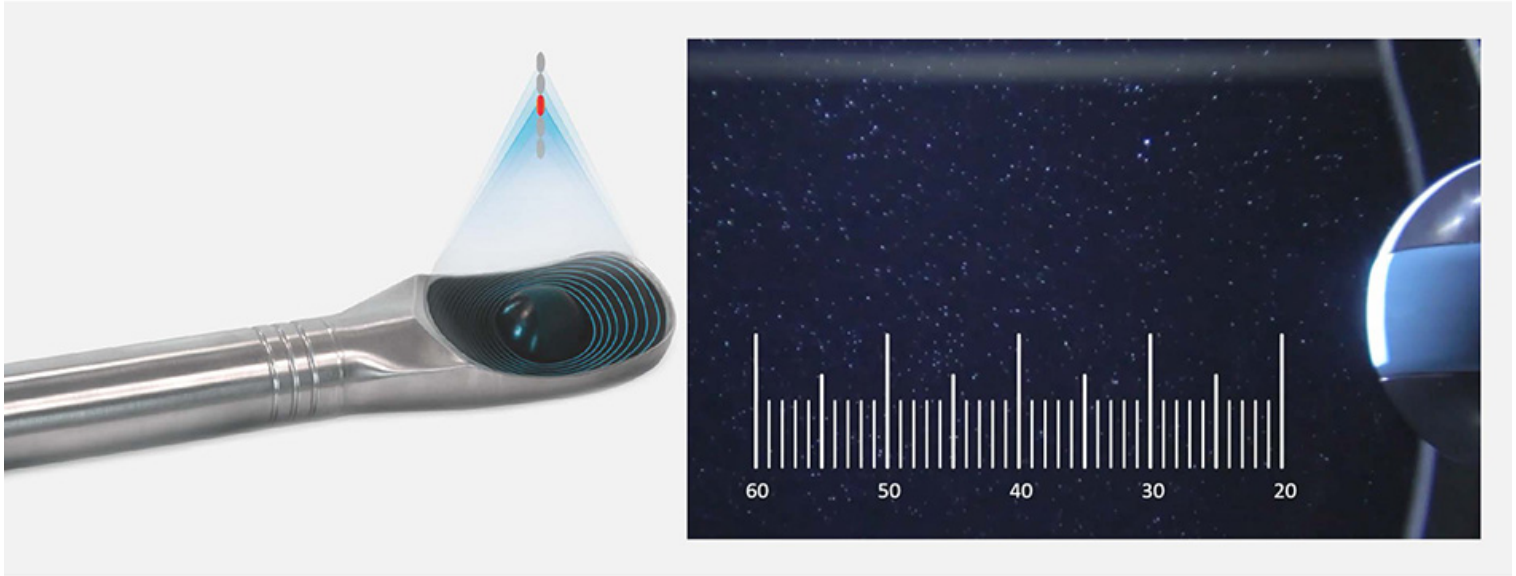
- Long Pulse (Continuous Wave)



Tissue Effect: Thermal Coagulative Necrosis in the Focal Zone; Surrounding Tissue Largely Spared

Histotripsy

Leveraging Focal One HIFU Transducer



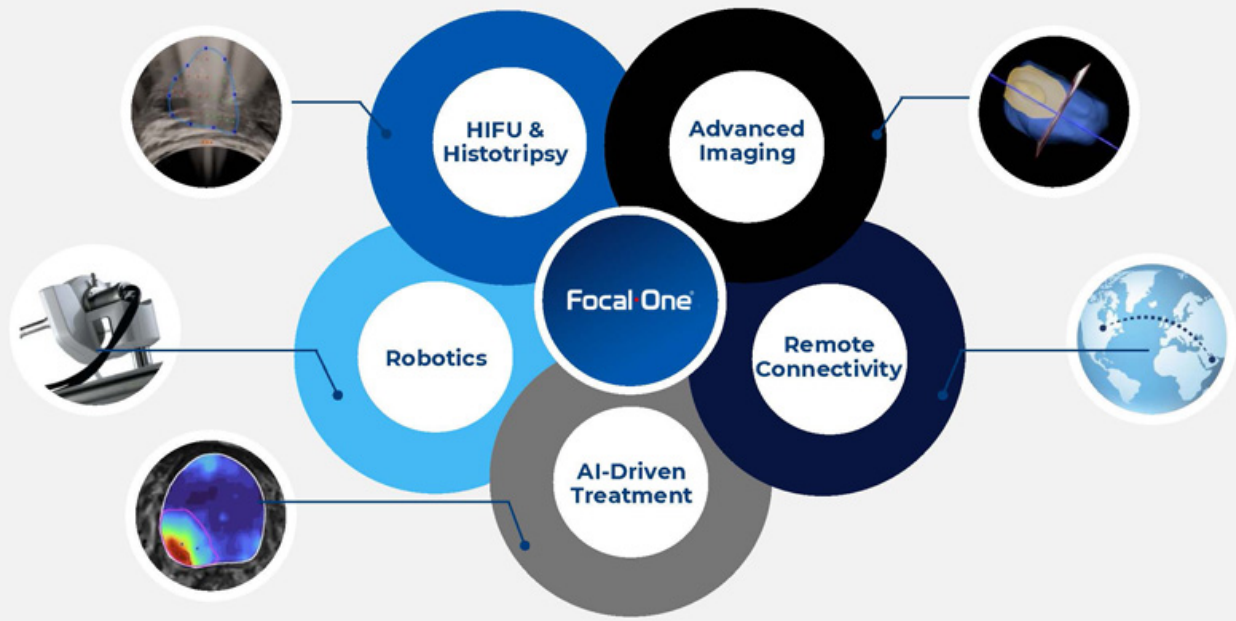
Histotripsy-related technologies and applications are under development and may require additional testing, validation, and regulatory authorization prior to commercialization.

Histotripsy

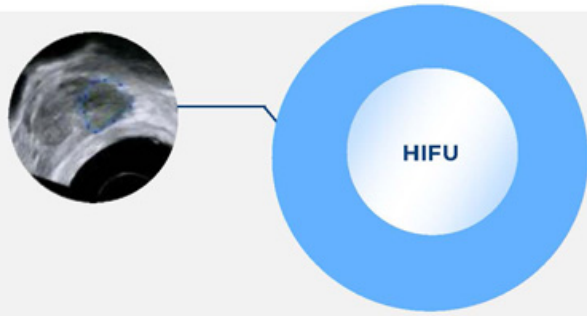
Leveraging Focal One Treatment Workflow



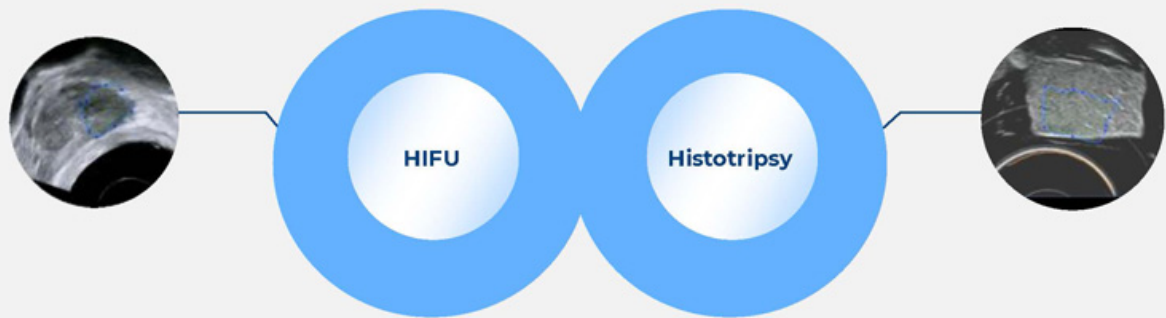
Scalable Focal One Platform Enables Simultaneous Innovation



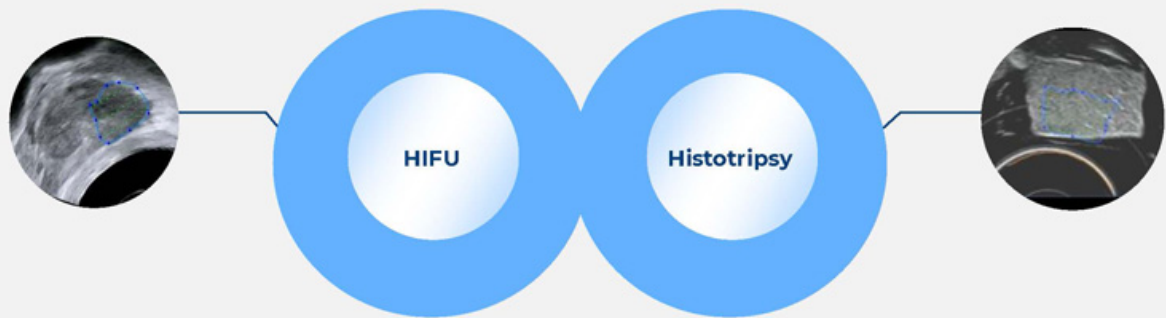
Focal One HIFU and Histotripsy



Focal One HIFU and Histotripsy

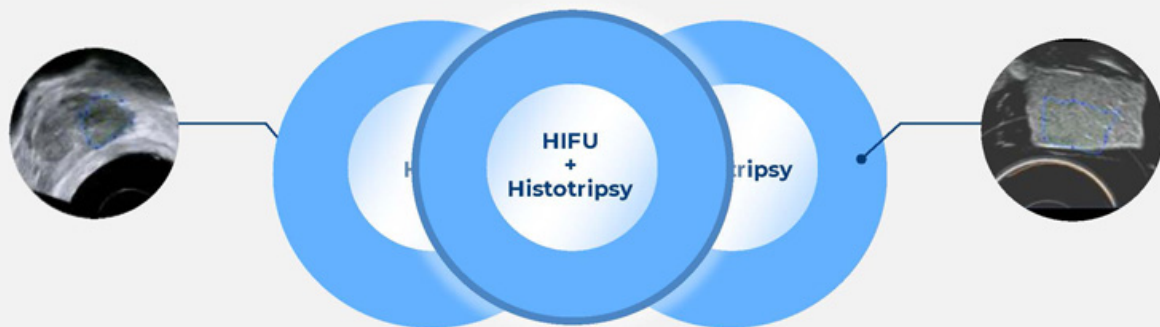


Focal One HIFU and Histotripsy

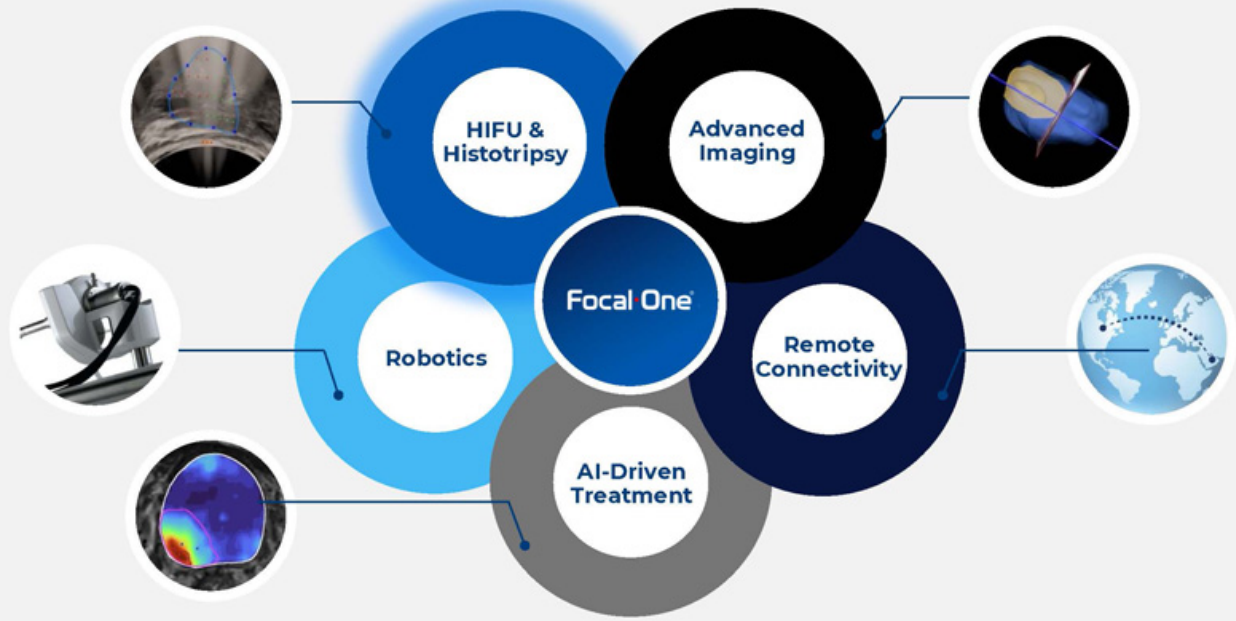


Focal One HIFU and Histotripsy

Actively Developing and Filing Novel Intellectual Property Covering The Unique Combination of HIFU and Histotripsy to Strengthen our IP Portfolio



Scalable Focal One Platform Enables Simultaneous Innovation



Focal One Robotic Focal Therapy Difference

Most Compatible

Precise Energy Delivery

Easiest to Learn, Use & Teach

Minimal OR Staffing

Shortest Treatment Times

Advanced Imaging with PSMA PET

Training and Telecollaboration via FocalConnect

AI-Assisted Treatment & Ablation Assessment

Expanding Focal One to a Single Platform to Treat Multiple Indications with a Combination of HIFU and Histotripsy

Positioned for Growth

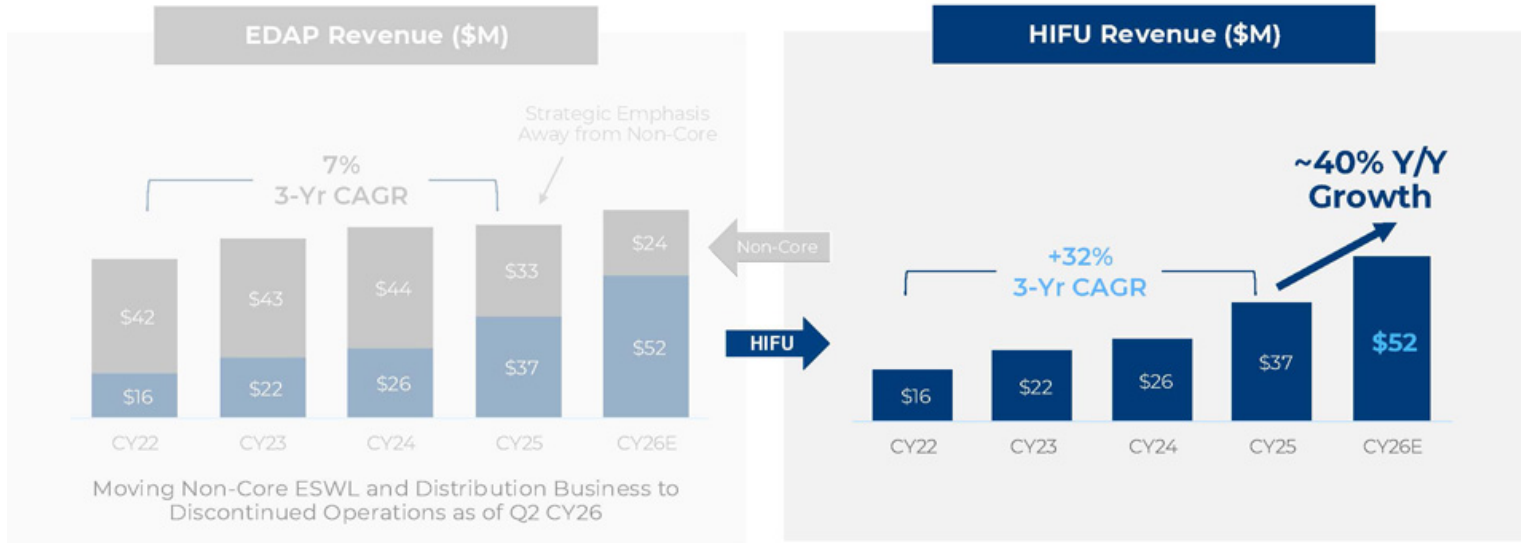
FocalTherics™

A Pure-Play HIFU Company

Ken Mobeck, CFO

Commitment to HIFU Portfolio

Accelerating Our Growth Engine

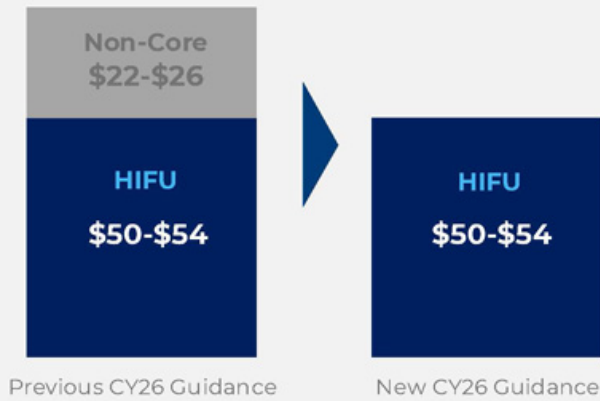


Note: CY26E = Midpoint of CY26 Guidance Range

CY 2026 Updated Revenue Guidance

Reiterating HIFU Only Guidance (Non-Core Classified to Discontinued Operations)

Revenue Guidance (\$M)



Benefits of HIFU Focus

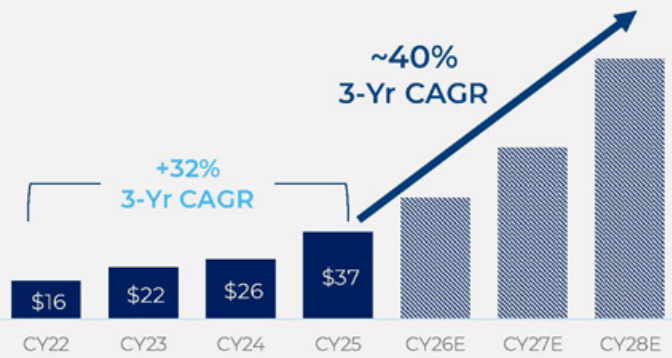
- **Accelerated** Revenue Growth
- **Higher** Gross Margins
- **Lower** Operating Expenses
- Pathway to **Operating Income Breakeven** in CY28

Long-Term Target Revenue Growth Model

Focal One System Placements & Procedure Volumes Remain Primary Catalysts

HIFU Revenue (\$M)

Growth Drivers



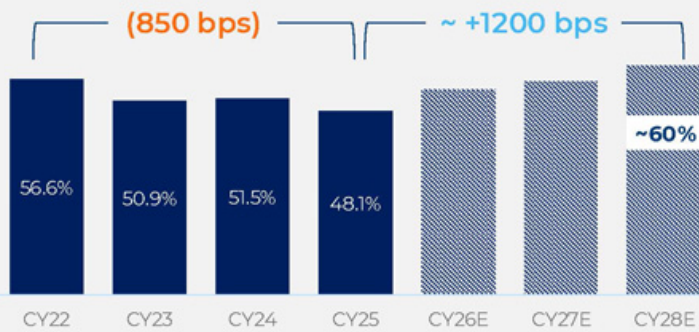
- Continued **Penetration** into Core U.S. Markets
- **International Expansion** into New Markets
- **Procedure** Volumes Growth
- Continued **Marketing Program** Development
- **New Indications** will Boost Procedures
- **Installed Base** Growth

Opportunities to Drive Operating Leverage

Levers to Drive HIFU Target Gross Margin to ~60%

HIFU Gross Margin (%)

Levers



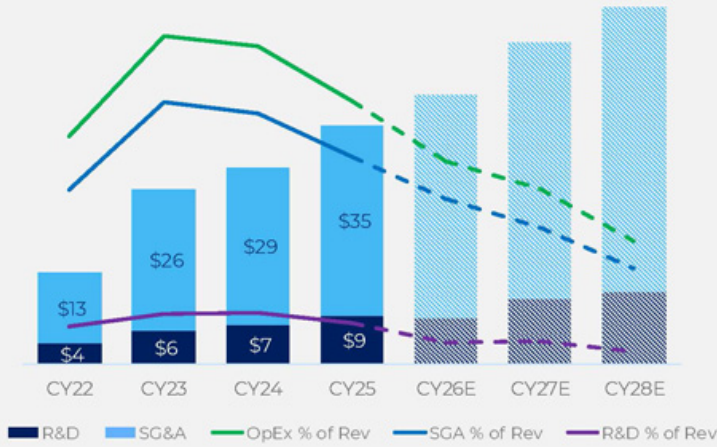
- Bill of Materials **Optimization**
- Continued Strong **Capital Unit** Growth
- **Procedure** Volumes Driving **Consumables**
- Maintain **Pricing** Discipline
- Enhanced **Capacity Utilization**

FocalTherics

Disciplined Operating Expense Investment

Operating Leverage Driven by Revenue Growth, Efficiency Gains and Platform Extendibility

HIFU Operating Expenses (\$M)



Priorities

- **R&D Investments** to Expand Indications and Unlock New Markets
 - **BPH**
 - **Artificial Intelligence**
 - **Histotripsy**
- **High Evidence Clinical Studies**
- SG&A Investment to Complete **Global Commercialization Build-Out**

2028E Target Model Financial Framework

Focused on Driving Positive EBITDA and Breakeven Operating Income to Deliver Shareholder Value

	CY25 Actual		CY28E Target Range
Revenue	\$37M		~ 40%+ 3-Yr CAGR (+/- 3%)
Gross Margin	48.1%		~60% (+/- 200 bps)
Operating Income	(\$21M)		Breakeven
EBITDA	(\$19M)		Positive
Installed Base	166		~ 30%+ 3-Yr CAGR (+/- 5%)

Note: E = Estimate

Closing Remarks

FocalTherics: Positioned For Strong Growth

**Large, Underserved
Growing Market**

**Differentiated Technology
Leading the Category of
Robotic Focal Therapy**

**Expanding Favorable
Reimbursement**

Robust Clinical Evidence

**Accelerated Global
Commercial Execution**

**Growing Revenue and
Pathway To Profitability**

Thank You

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